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UNITED STATES DISTRICT COURT
 NORTHERN DISTRICT OF CALIFORNIA

THE CITY AND COUNTY OF SAN FRANCISCO, CALIFORNIA and THE PEOPLE OF THE STATE OF CALIFORNIA,)	Case No. 3:18-cv-07591-CRB
Acting by and Through San Francisco City Attorney DENNIS J. HERRERA,)	FIRST AMENDED COMPLAINT FOR: (1)
)	VIOLATION OF RACKETEER
)	INFLUENCED AND CORRUPT
)	ORGANIZATIONS ACT (OPIOID
Plaintiffs,)	MARKETING ENTERPRISE); (2)
)	VIOLATION OF RACKETEER
vs.)	INFLUENCED AND CORRUPT
)	ORGANIZATIONS ACT (OPIOID SUPPLY
PURDUE PHARMA L.P., PURDUE PHARMA INC., THE PURDUE FREDERICK COMPANY, INC., RHODES PHARMACEUTICALS L.P., RICHARD S. SACKLER, JONATHAN D. SACKLER, MORTIMER D.A. SACKLER, KATHE A. SACKLER, ILENE SACKLER LEFCOURT, BEVERLY SACKLER, THERESA SACKLER, DAVID A. SACKLER, TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY, ALLERGAN PLC f/k/a ACTAVIS PLC, ALLERGAN FINANCE, LLC f/k/a ACTAVIS, INC. f/k/a WATSON)	CHAIN ENTERPRISE);(3) PUBLIC NUISANCE; (4) VIOLATION OF CALIFORNIA UNFAIR COMPETITION LAW; AND (5) VIOLATION OF CALIFORNIA FALSE ADVERTISING LAW
)	<u>DEMAND FOR JURY TRIAL</u>

[Caption continued on following page.]

1 PHARMACEUTICALS, INC., ALLERGAN)
SALES, LLC, ALLERGAN USA, INC.,)
2 WATSON LABORATORIES, INC.,)
WARNER CHILCOTT COMPANY, LLC,)
3 ACTAVIS PHARMA, INC. f/k/a/ WATSON)
PHARMA, INC., ACTAVIS SOUTH)
4 ATLANTIC LLC, ACTAVIS ELIZABETH)
LLC, ACTAVIS MID ATLANTIC LLC,)
5 ACTAVIS TOTOWA LLC, ACTAVIS LLC,)
ACTAVIS KADIAN LLC, ACTAVIS)
6 LABORATORIES UT, INC. f/k/a WATSON)
LABORATORIES, INC.-SALT LAKE CITY,)
7 ACTAVIS LABORATORIES FL, INC. f/k/a)
WATSON LABORATORIES, INC.-)
8 FLORIDA, TEVA PHARMACEUTICALS)
USA, INC., TEVA PHARMACEUTICAL)
9 INDUSTRIES LTD., CEPHALON, INC.,)
JOHNSON & JOHNSON, JANSSEN)
10 PHARMACEUTICALS, INC., NORAMCO,)
INC., ORTHO-MCNEIL-JANSSEN)
11 PHARMACEUTICALS, INC., JANSSEN)
PHARMACEUTICA, INC., ENDO HEALTH)
12 SOLUTIONS INC., ENDO)
PHARMACEUTICALS, INC., PAR)
13 PHARMACEUTICAL, INC., PAR)
PHARMACEUTICAL COMPANIES, INC.)
14 f/k/a PAR PHARMACEUTICAL HOLDINGS,)
INC., ENDO INTERNATIONAL PLC, INSYS)
15 THERAPEUTICS, INC., MALLINCKRODT)
PLC, MALLINCKRODT LLC, SPECGX)
16 LLC, AMERISOURCEBERGEN DRUG)
CORPORATION, ANDA, INC., CARDINAL)
17 HEALTH, INC., MCKESSON)
CORPORATION and WALGREEN CO.,)
18)
Defendants.)
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Plaintiffs the City and County of San Francisco (“San Francisco”) and the People of the State of California, acting by and through San Francisco City Attorney Dennis J. Herrera (the “People”) (collectively, “Plaintiffs”) bring this action to abate a present nuisance created by and to redress past violations by the following defendants (collectively, “Defendants”):

- Purdue Pharma L.P.; Purdue Pharma Inc.; The Purdue Frederick Company, Inc.; Richard S. Sackler; Jonathan D. Sackler; Mortimer D.A. Sackler; Kathe A. Sackler; Ilene Sackler Lefcourt; Beverly Sackler; Theresa Sackler; David A. Sackler; the Trust for the Benefit of Members of the Raymond Sackler Family; and Rhodes Pharmaceuticals L.P.;¹
- Cephalon, Inc.; Teva Pharmaceutical Industries Ltd.; and Teva Pharmaceuticals USA, Inc.;
- Janssen Pharmaceuticals, Inc. (formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica, Inc.); Johnson & Johnson; and Noramco, Inc.;
- Endo International plc; Endo Health Solutions Inc.; Endo Pharmaceuticals Inc.; Par Pharmaceutical, Inc.; and Par Pharmaceutical Companies, Inc. (formerly known as Par Pharmaceutical Holdings, Inc.);
- Insys Therapeutics, Inc.;²
- Mallinckrodt plc; Mallinckrodt LLC; and SpecGx LLC;
- Allergan plc (formerly known as Actavis plc); Allergan Finance, LLC (formerly known as Actavis, Inc., formerly known as Watson Pharmaceuticals, Inc.); Watson Laboratories, Inc.; Actavis Pharma, Inc. (formerly known as Watson Pharma, Inc.); Actavis LLC; Allergan Sales, LLC; Allergan USA, Inc.; Warner Chilcott Company, LLC; Actavis Elizabeth LLC; Actavis Mid Atlantic LLC; Actavis Kadian LLC; Actavis Totowa LLC; Actavis South Atlantic LLC; Actavis Laboratories UT, Inc. (formerly known as Watson Laboratories, Inc. – Salt Lake City); and Actavis Laboratories FL, Inc. (formerly known as Wat Laboratories, Inc. – Florida);
- AmerisourceBergen Drug Corporation;
- Cardinal Health, Inc.;

¹ The action against these defendants is currently stayed by virtue of their filing for bankruptcy in the U.S. Bankruptcy Court, Southern District of New York, in the case styled *In re Purdue Pharma L.P., et al.*, No. 19-23649.

² The action against Insys Therapeutics, Inc. is currently stayed by virtue of its filing for bankruptcy in the U.S. Bankruptcy Court, District of Delaware, in the case styled *In re Insys Therapeutics, Inc., et al.*, No. 19-11292.

- McKesson Corporation;
- Anda, Inc.; and
- Walgreen Co.

Plaintiffs assert the following claims:³

San Francisco brings a claim under the Racketeer Influenced and Corrupt Organizations (“RICO”) Act, 18 U.S.C. §1961 *et seq.*, against Purdue, Cephalon, Janssen, Endo, and Mallinckrodt for forming an illegal Opioid Marketing Enterprise and defrauding San Francisco. San Francisco also brings a RICO claim against Purdue, Cephalon, Endo, Mallinckrodt, Actavis, McKesson, Cardinal, Anda, and AmerisourceBergen for forming an illegal Opioid Supply Chain Enterprise and defrauding San Francisco. *See* Counts I and II. For these RICO claims, San Francisco seeks all legal and equitable relief as allowed by law, including, *inter alia*, actual damages; treble damages; equitable and/or injunctive relief in the form of court-supervised corrective communications, actions and programs; forfeiture as deemed proper by the Court; attorney’s fees; all costs and expenses of suit; and pre- and post-judgment interest.

The People bring a claim of public nuisance under California Civil Code §§3479-3480 against all Defendants seeking the costs of future abatement of the opioid-related public nuisance in San Francisco, which Defendants have caused. *See* Count III. The People also seek all other legal and equitable relief allowed by law.

The People also bring claims under the California Unfair Competition Law, Cal. Bus. & Prof. Code §17200 *et seq.*, against all Defendants except Walgreens for violations occurring within San Francisco, stemming from Defendants’ unlawful, unfair, or fraudulent practices in connection with the marketing, sale, and distribution of opioids. *See* Count IV. The People seek injunctive relief, restitution, and civil penalties.

Finally, the People bring claims under the False Advertising Law, Cal. Bus. & Prof. Code §17500 *et seq.*, against Purdue, Actavis, Cephalon, Janssen, Endo, Insys, Mallinckrodt, and the

³ Definitions of each of the Defendants referred to in this summary of claims are provided in §III of the “PARTIES” section below.

1 Sackler Defendants for violations occurring in San Francisco, stemming from their false or
 2 misleading statements made in connection with the sale of opioids. *See* Count V. The People seek
 3 injunctive relief, restitution, and civil penalties.⁴

4 INTRODUCTION AND FACTUAL BACKGROUND

5 1. This case arises from the worst man-made epidemic in modern medical history – the
 6 misuse, abuse, and over-prescription of opioids.

7 2. By now, most Americans have been affected, either directly or indirectly, by the
 8 opioid disaster. But few realize that this crisis arose from the opioid manufacturers’ deliberate
 9 marketing strategy together with distributors’ and pharmacies’ equally deliberate efforts to evade
 10 restrictions on opioid distribution and dispensing. Manufacturers, distributors, and pharmacy
 11 dispensers alike acted without regard for the lives that would be trampled in pursuit of profit.
 12

13 3. Since the push to expand prescription opioid use began in the late 1990s, the death
 14 toll has steadily climbed. The number of opioid overdose deaths in the United States rose from
 15 8,000 in 1999 to over 20,000 in 2009, and over 33,000 in 2015. In September 2017, opioid
 16 overdoses claimed nearly 48,000 lives.
 17

18 4. From 1999 through 2016, more than 350,000 people died from an overdose involving
 19 opioids. Well over half of those deaths – over 200,000 people – involved prescription opioids.
 20 These opioids include brand-name prescription medications like OxyContin, Opana ER, Vicodin,
 21 Subsys, and Duragesic, as well as generics like oxycodone, hydrocodone, and fentanyl.
 22

23
 24 ⁴ Plaintiffs file this First Amended Complaint without a redline to the previously operative
 25 complaint in this action as is typically required under this Court’s General Standing Order for Civil
 26 and Criminal Cases, Rule II.2. A redline here would create more confusion than clarity because
 27 Plaintiffs’ initial complaint was supplemented with a short form amended complaint in the MDL that
 28 incorporated by reference many of the parties, allegations, and claims from the Third Amended
 Complaint in *County of Summit, Ohio, et al., v. Purdue Pharma L.P., et al.*, Case No. 1:18-op-
 45090-DAP (N.D. Ohio Dec. 19, 2019) (“*Summit* Complaint”). Nevertheless, should the Court so
 request, Plaintiffs can submit a redline of the operative complaint in this action against the initial
 complaint in this action and/or the *Summit* Complaint, which the operative complaint closely tracks.

1 5. Most of the overdoses from non-prescription opioids are also directly related to
2 prescription opioids. Many opioid users who have become addicted to but are no longer able to
3 obtain opioids by prescription have turned to heroin. According to the American Society of
4 Addiction Medicine, 80% of people who initiated heroin use in the past decade started with
5 prescription painkillers – which, at the molecular level and in their effect, closely resemble heroin.
6 In fact, people who are addicted to prescription painkillers are 40 times more likely to become
7 addicted to heroin, and the CDC identifies addiction to prescription pain medication as the strongest
8 risk factor for heroin addiction.
9

10 6. In the words of Robert Anderson, who oversees death statistics at the Centers for
11 Disease Control and Prevention, ““I don’t think we’ve ever seen anything like this. Certainly not in
12 modern times.”” On October 27, 2017, the President declared the opioid epidemic a public health
13 emergency.
14

15 7. This suit takes aim at the two primary causes of the opioid crisis in San Francisco:
16 (a) a marketing scheme involving the false and deceptive marketing of prescription opioids, which
17 was designed to dramatically increase the demand for and sale of opioids and opioid prescriptions;
18 and (b) a supply chain scheme, pursuant to which the various entities in the supply chain failed to
19 design and operate systems to identify suspicious orders of prescription opioids, maintain effective
20 controls against diversion, and halt distribution and dispensing of suspicious orders, thereby
21 contributing to the oversupply of such drugs and fueling an illegal secondary market.
22

23 8. On the demand side, the crisis was precipitated by the defendants who manufacture,
24 sell, and market prescription opioid painkillers (“Marketing Defendants”). Through a massive
25 marketing campaign premised on false and incomplete information, the Marketing Defendants
26 engineered a dramatic shift in how and when opioids are prescribed by the medical community and
27 used by patients. The Marketing Defendants relentlessly and methodically, but untruthfully, asserted
28

1 that the risk of addiction was low when opioids were used to treat chronic pain, and overstated the
2 benefits and trivialized the risks of the long-term use of opioids.

3 9. The Marketing Defendants' goal was simple: to dramatically increase sales by
4 convincing doctors to prescribe opioids not only for the kind of severe pain associated with cancer or
5 short-term post-operative pain, but also for common chronic pain, including back pain and arthritis.
6 They did this even though they knew that opioids were addictive and subject to abuse, and that their
7 other claims regarding the risks, benefits, and superiority of opioids for long-term use were untrue
8 and unfounded.

10 10. From the day they made the pills to the day those pills were consumed, these
11 manufacturers had control over the information regarding addiction they chose to spread and
12 emphasize, or omit, as part of their massive marketing campaign in San Francisco. By providing
13 misleading information to doctors about addiction being rare and opioids being safe even for
14 everyday use and in high doses, then pressuring them into prescribing their products by arguing,
15 among other things, that no one should be in pain, the Marketing Defendants created a population of
16 addicted patients who sought opioids at never-before-seen rates. The scheme worked, and through it
17 the Marketing Defendants caused their profits to soar as more and more people became dependent on
18 opioids.

20 11. Through their publications and websites, endless stream of sales representatives,
21 "education" programs, and other means, the Marketing Defendants dramatically increased their sales
22 of prescription opioids and reaped billions of dollars of profit as a result. Since 1999, the amount of
23 prescription opioids sold in the United States nearly quadrupled. In 2016, 289 million prescriptions
24 for opioids were filled in the United States – enough to medicate every adult in America around the
25 clock for a month.

1 12. The crisis was also fueled and sustained by those involved in the supply chain of
 2 opioids, including manufacturers, distributors, and pharmacies, who failed to maintain effective
 3 controls over the distribution of prescription opioids, and who instead have actively sought to evade
 4 such controls. Defendants have contributed substantially to the opioid crisis by selling, distributing,
 5 and dispensing far greater quantities of prescription opioids than they know could be necessary for
 6 legitimate medical uses, while failing to report, and to take steps to halt, suspicious orders, thereby
 7 exacerbating the oversupply of such drugs and fueling an illegal secondary market.

9 13. As many as one in four patients who receive prescription opioids long-term for
 10 chronic pain in a primary care setting struggles with addiction. In 2014, almost two million
 11 Americans were addicted to prescription opioids and another 600,000 to heroin. From 1999 to 2016,
 12 more than 200,000 people died in the United States from overdoses related to prescription opioids –
 13 more than three times the number of Americans who died in the Vietnam war. Overdose deaths
 14 involving prescription opioids were six times higher in 2017 than 1999.

16 14. As a direct and foreseeable result of Defendants’ conduct, cities and counties across
 17 the nation, including San Francisco, are now swept up in what the Centers for Disease Control
 18 (“CDC”) has called a “public health epidemic” and what the U.S. Surgeon General has deemed an
 19 “urgent health crisis.”⁵ The increased volume of opioid prescribing correlates directly to
 20 skyrocketing addiction, overdose and death; black markets for diverted prescription opioids; and a
 21 concomitant rise in heroin and fentanyl abuse by individuals who can no longer legally acquire or
 22 simply cannot afford prescription opioids.

25
 26 ⁵ *Examining the Growing Problems of Prescription Drug and Heroin Abuse*, Ctrs. For Disease
 27 Control and Prevention (Apr. 29, 2014), <https://www.cdc.gov/washington/testimony/2014/t20140429.htm>; *see also* Letter from Vivek H. Murthy, Surgeon General, American Academy
 28 of Family Physicians (Aug. 2016), https://www.aafp.org/patient-care/public-health/pain-opioids/turn_the_tide.html.

1 15. Thus, rather than compassionately helping patients, the explosion in opioid use and
 2 Defendants' profits have come at the expense of patients and have caused ongoing harm and damage
 3 to San Francisco. As a former CDC director concluded: "We know of no other medication routinely
 4 used for a nonfatal condition that kills patients so frequently."⁶

5 16. Defendants' conduct has had severe and far-reaching public health and social service
 6 consequences, including the fueling of addiction and overdose from illicit drugs such as heroin and
 7 fentanyl. The costs are borne by San Francisco and other governmental entities. These necessary
 8 and costly responses to the opioid crisis imposed on San Francisco include, for example, the
 9 handling of emergency responses to overdoses; providing addiction treatment; keeping public spaces
 10 free of dangerous syringes; and autopsying the dead, among others.

11 17. The burdens imposed on San Francisco are not only the normal or typical burdens
 12 associated with government programs and services. Rather, they also include extraordinary costs
 13 and losses greatly in excess of the norm that are related directly to Defendants' illegal actions.
 14 Defendants' conduct has created a public nuisance. San Francisco has been severely strained by this
 15 public health crisis.

16 18. California, like many states across the country, is facing an unprecedented opioid
 17 addiction epidemic. In 2017, there were nearly 22 million opioid prescriptions in California.⁷ The
 18 opioid addiction epidemic claimed the lives of more than 2,190 Californians in 2017.⁸ That same
 19 year saw opioid overdoses straining California hospitals with 4,281 emergency room visits.⁹

20
 21
 22
 23 ⁶ Thomas R. Frieden, M.D., M.P.H., & Debra Houry, M.D., M.P.H., *Reducing the Risks of Relief*
 24 *– The CDC Opioid-Prescribing Guideline*, 374 New England Journal of Medicine 1501-04 (Apr.
 21, 2016), <https://www.nejm.org/doi/full/10.1056/NEJMp1515917>.

25 ⁷ *2017 California Opioid Overdose Surveillance Dashboard*, California Department of Public
 26 Health, <https://discovery.cdph.ca.gov/CDIC/ODdash/> (last visited Mar. 13, 2020).

27 ⁸ *Id.*

28 ⁹ *Id.*

19. As set forth more fully below, San Francisco, specifically, has also been severely affected by the opioid epidemic. From 2010 through 2012, approximately 331 individuals died in San Francisco from accidental overdose caused by opioids (310 involving prescription opioids and 31 involving heroin).¹⁰ Between 2016 and 2018, San Francisco saw a 70% increase in opioid-related overdose deaths.¹¹ And in 2019, the City's fatal fentanyl overdoses more than doubled. The opioid epidemic is evidenced not only by the overdose death rate, but also by the alarming opioid addiction rate. San Francisco's first responders, healthcare and other professionals, including even librarians, are grappling with the devastating effects of this epidemic on a daily basis.

20. Many of the Defendants have not fully changed their ways or corrected their past misconduct, but are instead continuing to fuel the crisis.

21. Within the next hour, six Americans will die from opioid overdoses, and drug manufacturers will earn over \$2.7 million from the sale of opioids.

22. Plaintiffs bring this suit to bring the devastating march of this epidemic to a halt and to hold Defendants responsible for the crisis they caused, including by paying the costs of abating it in San Francisco.

A. Defendants' False and Misleading Marketing and Failure to Report and Halt Suspicious Orders of Opioids Fueled the Opioid Crisis Nationally and in San Francisco

23. Drug manufacturers' deceptive marketing and sale of opioids to treat chronic pain is one of the main drivers of the opioid epidemic. Historically, prescription opioids had been used for short-term, post-surgical and trauma-related pain, and for palliative end-of-life care primarily in

¹⁰ Adam J. Visconti et al. *Opioid Overdose Deaths in the City and County of San Francisco: Prevalence Distribution, and Disparities*, 92 J. Urb. Health 758-72 (Aug. 2015), <https://www.ncbi.nlm.nih.gov/pubmed/26077643>.

¹¹ Dr. Phillip O. Coffin, et al. *Substance Use Trends in San Francisco Through 2018* 10 (Dec. 2019), <https://ndews.umd.edu/sites/ndews.umd.edu/files/San-Francisco-Substance-Use-2019-Annual-Report-Trends-Through-2018.pdf>.

1 cancer patients. Because opioids are highly addictive and dangerous, the Food and Drug
2 Administration (“FDA”) regulates them as Schedule II Controlled Substances, *i.e.*, drugs that have a
3 high potential for abuse and that may lead to severe psychological or physical dependence.

4 24. This demonstrated need for caution comports with the historical understanding of
5 both the medical community and the American culture at large regarding the serious consequences
6 of opioid use and misuse. Indeed, thousands of years of experience have taught that opioids’ ability
7 to relieve pain comes at a steep price; opioids are dangerously addictive and often lethal substances.
8 For generations, physicians were taught that opioid painkillers were highly addictive and should be
9 used sparingly and primarily for patients near death.¹² The medical community also understood that
10 opioids were poorly suited for long-term use because tolerance would require escalating doses and
11 dependence would make it extremely difficult to discontinue their use.
12

13 25. The prevailing and accurate understanding of the enormous risks and limited benefits
14 of long-term opioid use constrained drug manufacturers’ ability to drive sales. In order to decrease
15 reasonable concerns about opioids and to maximize profits, opioid manufacturers, including the
16 Marketing Defendants engaged in a concerted, coordinated strategy to shift the way in which doctors
17 and patients think about pain and, specifically, to encourage the use of opioids to treat not just the
18 relative few who suffer from acute post-surgical pain and end-stage cancer pain, but the masses who
19 suffer from common chronic pain conditions. This strategy was implemented nationally, including
20 in San Francisco.
21

22 26. Borrowing from the tobacco industry’s playbook, the Marketing Defendants
23 employed ingenious marketing strategies, as detailed further herein, designed to “reeducate” the
24 public and prescribers. The Marketing Defendants deliberately conceived these strategies to create,
25
26

27 ¹² Harriet Ryan et al., *OxyContin goes global – “We’re only just getting started,”* L.A. Times (Dec.
28 18, 2016), <http://www.latimes.com/projects/la-me-oxycontin-part3/>.

1 and in fact did create, an entirely new “health care” narrative – one in which opioids are considered
 2 safe and effective for long-term use and pain is aggressively treated at all costs. According to this
 3 newly fabricated narrative, pain was seriously under-treated throughout the United States because
 4 opioids were under-prescribed, and doctors came under enormous pressure to treat all kinds of pain
 5 with opioids.
 6

7 27. The Marketing Defendants’ intention was to normalize aggressive prescribing of
 8 opioids for various kinds of pain by downplaying the substantial risks of opioids, especially the risk
 9 of addiction, and by exaggerating opioid benefits. To accomplish this goal, they intentionally misled
 10 doctors and patients about the appropriate uses, risks, safety and efficacy of prescription opioids.
 11 They did so directly through sales representatives and marketing materials and indirectly through
 12 financial relationships with academic physicians, professional societies, hospitals, trade associations
 13 for state medical boards and seemingly neutral third-party foundations.
 14

15 28. False messages about the safety, addictiveness and efficacy were disseminated by
 16 infiltrating professional medical societies and crafting and influencing industry guidelines in order to
 17 disseminate false and deceptive pro-opioid communiques under the guise of science and truth.
 18 According to a February 2018 report issued by then-U.S. Senator Claire McCaskill, opioid
 19 manufacturers, including several of the Marketing Defendants here, paid nearly \$9 million between
 20 2012 and 2017 to advocacy groups and professional societies operating in the area of opioids
 21 policy.¹³ As discussed below, the manufacturers got their money’s worth.
 22

23 29. Initiatives from the groups in this report often echoed and amplified messages
 24 favorable to increased opioid use – and ultimately, the financial interests of opioid manufacturers.
 25

26 ¹³ *Fueling an Epidemic, Report Two: Exposing the Financial Ties Between Opioid Manufacturers*
 27 *and Third-Party Advocacy Groups*, U.S. Senate Homeland Security & Governmental Affairs
 28 Committee, Ranking Member’s Office at 1 (Feb. 13, 2018), <https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20Epidemic-Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Party%20Advocacy%20Groups.pdf>.

1 These groups have issued guidelines and policies minimizing the risk of opioid addiction and
 2 promoting opioids for chronic pain, lobbied to change laws directed at curbing opioid use, and
 3 argued against accountability for physicians and industry executives responsible for overprescription
 4 and misbranding. The purportedly neutral medical societies also “strongly criticized 2016 guidelines
 5 from the . . . (CDC) that recommended limits on opioid prescriptions for chronic pain,” which
 6 Senator McCaskill’s report described as “a key federal response to the ongoing epidemic.” In
 7 conclusion, the report found “a direct link between corporate donations and the advancement of
 8 opioids-friendly messaging.”

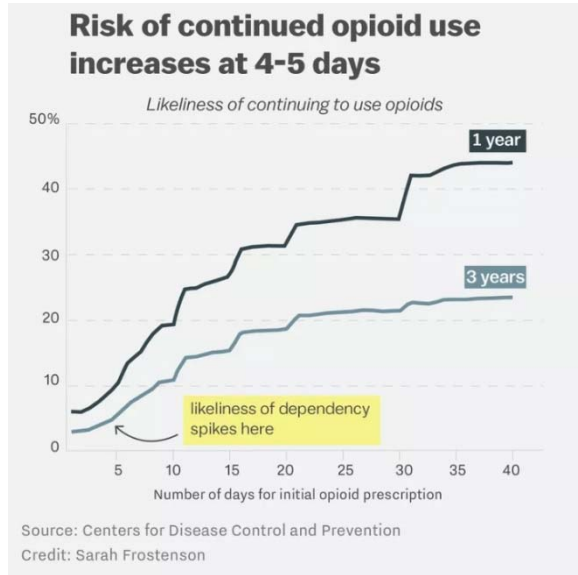
10 30. The Marketing Defendants assured the public and prescribers – nationally and in San
 11 Francisco – that the risk of becoming addicted to prescription opioids among patients being treated
 12 for pain was less than 1%. In reality, many people with no addiction history can become addicted
 13 after just weeks or even days of use.¹⁴ According to one study, as many as 56% of patients receiving
 14 long-term prescription opioid painkillers become addicted.¹⁵ Indeed, almost one in five people who
 15 receive an opioid prescription with ten days’ supply will still be taking opioids one year later.¹⁶ The
 16 following chart illustrates the degree to which the risk of dependency escalates based on the length
 17 of time for which the patient receives an initial opioid prescription:¹⁷

21 ¹⁴ Anna Lembke, *Drug Dealer, MD: How Doctors Were Duped, Patients Got Hooked, and Why It’s So Hard to Stop* 22 (Johns Hopkins University Press 2016).

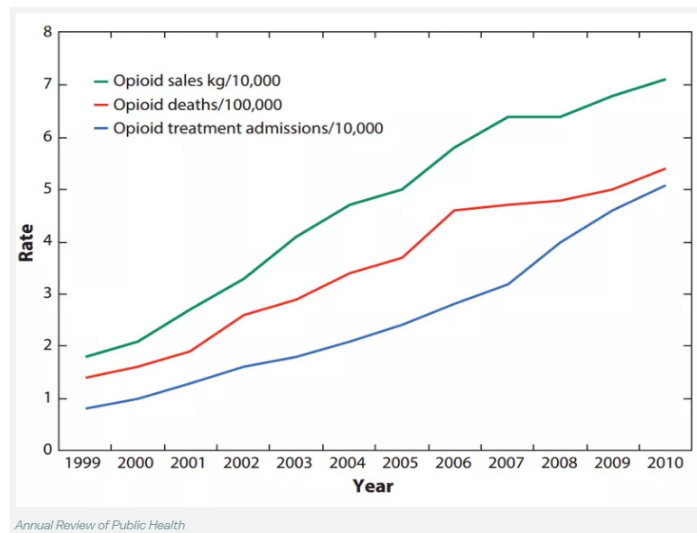
22 ¹⁵ Bridget A. Martell et al., *Systematic Review: Opioid Treatment for Chronic Back Pain: Prevalence, Efficacy, and Association with Addiction*, 146(2) Ann. Intern. Med. 116-27 (2007),
 23 <http://annals.org/aim/article/732048/systematic-review-opioid-treatment-chronic-back-pain-prevalence-efficacy-association>.

24 ¹⁶ Sarah Frostenson, *The risk of a single 5-day opioid prescription, in one chart*, Vox (Mar. 18, 2017, 7:30 AM), www.vox.com/2017/3/18/14954626/one-simple-way-to-curb-opioid-overuse-prescribe-them-for-3-days-or-less.

25 ¹⁷ German Lopez & Sarah Frostenson, *How the opioid epidemic became America’s worst drug crisis ever, in 15 maps and charts*, Vox (Mar. 29, 2017), <http://www.vox.com/science-andhealth/2017/3/23/14987892/opioid-heroin-epidemic-charts>.



31. The Marketing Defendants' focus on driving opioid sales growth led to concomitant growth in the number of deaths resulting from opioid use and in hospital admissions for opioid-related addiction treatment:¹⁸



32. Put simply, the Marketing Defendants manipulated and misrepresented medical science to serve their own agenda at the cost of human lives and health. Indeed, in a study published

¹⁸ Andrew Kolodny et al., *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, 36 Annu. Rev. Public Health 559-74 (2015), <http://www.annualreviews.org/doi/pdf/10.1146/annurev-publhealth-031914-122957>.

1 on March 6, 2018 in the *Journal of the American Medical Association* (“JAMA”),¹⁹ researchers who
 2 conducted the first randomized clinical trial designed to compare the efficacy of opioids and non-
 3 opioids, such as acetaminophen, ibuprofen and lidocaine, for the treatment of moderate to severe
 4 back pain, hip pain or knee osteoarthritis pain, concluded that patients who took opioids over the
 5 long term experienced improvements in pain-related function no better than patients who used safer
 6 alternatives with little or no risk of addiction or dependency.

8 33. The Distributor Defendants (defined below) are major distributors of controlled
 9 substances that act as middlemen between drug companies and pharmacies. In addition to its role as
 10 a major distributor of controlled substances, Walgreen Co. (“Walgreens”) also operates a national
 11 pharmacy chain whose pharmacies are responsible for dispensing the majority of all prescription
 12 opioids dispensed in San Francisco. Like the Marketing Defendants, the Distributor Defendants (and
 13 Walgreens, in its additional role as a dispensing defendant), were aware of a growing epidemic
 14 arising from the addiction to, and abuse of, prescription opioids they supplied. Defendants were
 15 aware of the quantities and frequency with which those drugs were distributed to and dispensed by
 16 entities in San Francisco. However, Defendants failed to report suspicious sales, as required by state
 17 and federal law. Their failure to follow the law fueled the flood of pills into and significantly
 18 contributed to rising addiction and overdose rates in San Francisco.

20 34. As further evidence of their malfeasance, the country’s major opioid distributors and
 21 dispensaries have paid hefty fines for their failure to report suspicious orders as required by law.
 22 McKesson Corporation (“McKesson”), based in San Francisco until April 2019, and the largest
 23 prescription drug wholesale company in the United States, agreed on January 17, 2017, to pay a
 24 \$150 million fine to the federal government. In December 2016, Cardinal Health, Inc. (“Cardinal”)
 25

26
 27 ¹⁹ Erin E. Krebs et al., *Effect of Opioid vs Nonopioid Medications on Pain-Related Function in*
 28 *Patients with Chronic Back Pain or Hip or Knee Osteoarthritis Pain: The SPACE Randomized*
Clinical Trial, 319(9) JAMA 872-82 (Mar. 6, 2018).

1 reached a \$44 million settlement with the federal government. One month later, Cardinal reached a
 2 \$20 million settlement with the State of West Virginia. AmerisourceBergen Drug Corporation
 3 (“AmerisourceBergen”) also agreed to pay West Virginia \$16 million in 2017.²⁰ And in June 2013,
 4 Walgreens, which dispenses more opioids in San Francisco than any other pharmacy, paid a then-
 5 record \$80 million in civil penalties to resolve multiple open investigations alleging “an
 6 unprecedented number of record-keeping and dispensing violations” of the Comprehensive Drug
 7 Abuse Prevention and Control Act of 1970 (“CSA” or “Controlled Substances Act”), 21 U.S.C. §801
 8 *et seq.* As part of the settlement, Walgreens admitted it failed to uphold its obligations as a CSA
 9 registrant.²¹

11 35. Notwithstanding these fines and settlements, Defendants’ scheme was tremendously
 12 successful, if measured by profit. According to *Fortune* magazine, McKesson, AmerisourceBergen,
 13 Cardinal, and Walgreens are each among the top 17 companies in the Fortune 500. The Sackler
 14 family, which owns Purdue (defined below) – a privately held company – is listed on *Fortune*’s list
 15 of America’s wealthiest families; its “ruthless marketing of painkillers has generated billions of
 16 dollars – and millions of addicts.”²²

18 36. The impact of opioid addiction has devastated the nation, emerging as one of the
 19 country’s, and San Francisco’s, most severe health threats. Former FDA Commissioner David A.
 20 Kessler has called the failure to recognize the dangers of painkillers “one of the biggest mistakes in
 21

23 ²⁰ Charles Ornstein, *Drug Distributors Penalized For Turning Blind Eye In Opioid Epidemic*,
 24 National Public Radio (Jan. 27, 2017), <http://www.npr.org/sections/health-shots/2017/01/27/511858862/drug-distributors-penalized-for-turning-blind-eye-in-opioid-epidemic>.

25 ²¹ Press Release, U.S. Department of Justice, *Walgreens Agrees To Pay A Record Settlement Of*
 26 *\$80 Million For Civil Penalties Under The Controlled Substances Act* (June 11, 2013)
<https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-record-settlement-80-million-civil-penalties-under-controlled>.

27 ²² Patrick Radden Keefe, *The Family That Built an Empire of Pain*, *The New Yorker* (Oct. 30,
 28 2017), <https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain>.

1 modern medicine.” As alleged herein, that “mistake” resulted in large part from Defendants’ false
 2 and misleading messaging, which was carefully calculated to reach as many prescribers as possible,
 3 as well as Defendants’ willingness to turn a blind eye to suspicious orders.

4 37. Even where some Defendants have previously been forced to admit the unlawful
 5 marketing and sale of opioids and/or the failure to report suspicious orders, they have not ceased
 6 their conduct. The profits realized by aggressive and unsupported opioid marketing, distribution,
 7 and dispensing dwarf the penalties imposed as a result of violations found. Thus, the incentive to
 8 push opioids remains. For example, despite the clear and obvious devastation it caused at home, in
 9 2016 Purdue’s owners boasted they would pursue the same ubiquity abroad. As reported by the *Los*
 10 *Angeles Times* in 2016, Purdue stated “[w]e’re only just getting started,” and intended to “[p]ut the
 11 painkiller that set off the U.S. opioid crisis into medicine cabinets around the world.” “A network of
 12 international companies owned by the family is moving rapidly into Latin America, Asia, the Middle
 13 East, Africa and other regions, and pushing for broad use of painkillers in places ill-prepared to deal
 14 with the ravages of opioid abuse and addiction.”²³

17 **B. The Devastating Effects of the Opioid Crisis in San Francisco**

18 38. Defendants’ marketing and compliance were driven by national policies, plans, and
 19 procedures that were the same in San Francisco as they were nationwide.

20 39. Upon information and belief, sales representatives from each of the Marketing
 21 Defendants visited prescribers in San Francisco. For example, based on an analysis of publicly
 22 disclosed reports from the years 2013 through 2016, Purdue and Janssen (defined below) paid nearly
 23 \$1.5 million and more than \$740,000, respectively, for expenses to San Francisco physicians that
 24 included “food and beverage,” “charitable contribution,” “travel and lodging” and “consulting fee,”
 25 among other types of expenses.

27 ²³ Harriet Ryan et al., *OxyContin goes global – “We’re only just getting started,”* L.A. Times (Dec.
 28 18, 2016), <http://www.latimes.com/projects/la-me-oxycontin-part3/>.

40. The Marketing Defendants' marketing activities were successful in driving the sale of the Marketing Defendants' opioids in San Francisco. According to publicly available ARCOS data, between 2006 and 2014, inclusive, the Marketing Defendants sold opioids in San Francisco totaling more than 3.68 billion morphine milligram equivalents ("MME").

Defendant	SF MME (2006-2014)	SF Market Share by MME (2006-2014)
Actavis	1,187,268,332	24.1%
SpecGx LLC	914,281,549	18.6%
Purdue	846,418,006	17.2%
Par Pharmaceutical	280,812,069	5.7%
Janssen	178,384,287	3.6%
Rhodes	153,395,674	3.1%
Teva	124,215,268	2.5%
Total	3,684,775,185	74.8%

41. The San Francisco market for the most widely prescribed opioids, oxycodone and hydrocodone, was dominated by the Marketing Defendants during the same time period.

42. For oxycodone, measured by MME, Purdue had a 40.6% market share, Actavis (defined below) a 24.3% market share, SpecGx LLC a 16.3% market share, Par Pharmaceutical (defined below) a 6.0% market share, and Teva (defined below) a 3.6% market share, together comprising 90.8% of all oxycodone sold in San Francisco from 2006 to 2014, inclusive.

43. For hydrocodone, measured by MME, Actavis had a 54.4% market share, SpecGx a 22.0% market share, and Par Pharmaceutical a 10.5% market share, comprising 86.9% of all hydrocodone sold in San Francisco from 2006 to 2014, inclusive.

44. The Marketing Defendants were also responsible for substantial majorities, measured by MME, of other opioids sold in San Francisco between 2006 and 2014, inclusive. By way of example, for morphine, SpecGx had a 33.1% market share, Actavis a 19.2% market share, Rhodes (defined below) a 13.5% market share, Par Pharmaceutical an 8.0% market share, and Purdue a 1.3% market share, together comprising 75.1% of the morphine sold during that time period; and for

1 oxymorphone, Endo (defined below) had an 88.8% market share, Actavis had a 1.8% market share,
 2 and Teva had a 1.1% market share, together comprising 91.7% of the oxymorphone sold during that
 3 time period.

4 45. The Distributor Defendants were the overwhelming source of prescription opioids
 5 distributed for sale to San Francisco residents. According to publicly available ARCOS data,
 6 AmerisourceBergen, McKesson, Cardinal, Walgreens, and Anda, Inc. distributed more than 244
 7 million opioid dosage units and more than 4.5 billion MME of opioids in San Francisco between
 8 2006 and 2014, inclusive, representing approximately 90% of all opioids distributed in San
 9 Francisco during that time.

Company Name	Market Share (Units)	Total Dosage (Units)	Market Share (MME)	Total Dosage (MME)
Walgreens	33.68%	93,682,275	27.63%	1,360,474,386
McKesson	27.91%	77,635,350	24.60%	1,211,688,348
AmerisourceBergen	17.90%	49,790,665	28.09%	1,383,503,558
Cardinal	7.44%	20,696,632	9.69%	477,257,094
Anda	0.96%	2,659,892	2.57%	126,769,563
Total	87.89%	244,464,814	92.58%	4,559,692,949

18 46. Statewide, the volume of opioids – a portion of which foreseeably migrated into San
 19 Francisco – is in the multiple billions of dosage units. Distributors registered with the DEA moved
 20 more than 2.3 billion units²⁴ of these opioids into the State of California between 2006 and 2014,
 21 inclusive. Of those, the Distributor Defendants delivered more than 2 billion,²⁵ approximately 88%
 22 of all opioids distributed for sale statewide.

24 47. Moreover, Walgreens pharmacies comprised 55 of the top 100 dispensing pharmacies
 25 in San Francisco from 2006 to 2014, inclusive, when measured by MME. During that time period,

26
 27 ²⁴ The total is 2,327,896,863.

28 ²⁵ The total is 2,041,819,495.

1 those 55 Walgreens pharmacies alone ordered more than 108 million dosage units of opioids,
2 reflecting more than 1.77 billion MME.

3 48. This information, along with information known only to Defendants, would have
4 alerted them to potentially suspicious orders of opioids in and affecting San Francisco.

5 49. Upon information and belief, the national conduct of Defendants previously described
6 also occurred in San Francisco. Plaintiffs' information and belief rests upon the following facts:

7 (a) Pharmacies, wholesalers and manufacturers have access to detailed
8 transaction-level data on the sale and distribution of opioids, which can be broken down by zip code,
9 prescriber, and pharmacy and includes the volume of opioids, dose, and the distribution of other
10 controlled and non-controlled substances;

11 (b) Manufacturers make use of that data to target their marketing and, for that
12 purpose, regularly monitor the activity of doctors and pharmacies;

13 (c) Manufacturers and distributors regularly visit pharmacies and doctors to
14 promote and provide their products and services, which allows them to observe red flags of
15 diversion;

16 (d) The Distributor Defendants were the primary source of prescription opioids in
17 San Francisco, and each plays such a large part in the distribution of opioids that its own volume
18 provides a ready vehicle for measuring the overall flow of opioids into a pharmacy or geographic
19 area;

20 (e) Several national retail pharmacies, including Walgreens, have been penalized
21 for their illegal prescription opioid practices, and the wide-spread nature of these violations suggests
22 they are the product of national policies and practices, including the performance metrics and
23 prescription quotas adopted for their retail stores;

1 (f) Walgreens distributed opioids solely to its own pharmacies, and therefore had
 2 full access to detailed information from those pharmacies about opioid orders sufficient to alert it to
 3 suspicious orders;

4 (g) Mallinckrodt (defined below), the Distributor Defendants, and Walgreens (in
 5 its role as both a distributor and a dispenser) have admitted to or been subject to enforcement actions
 6 for systemic failures in their compliance with controlled substances obligations, from which its
 7 actions in San Francisco would not have been exempt; and

8 (h) The Marketing Defendants purchased chargeback data that allowed them to
 9 monitor the combined flow of opioids into a pharmacy or geographic area and/or detailed
 10 information about prescribing habits from IMS Health.²⁶

11
 12 50. Each of the Defendants disregarded their reporting and due diligence obligations
 13 under federal and California law in and affecting San Francisco. The Defendants consistently failed
 14 to report or suspend illicit orders, deepening the crisis of opioid abuse, addiction, and death in San
 15 Francisco.

16
 17 51. This conduct also has been confirmed, in material ways, by the activities observed in
 18 San Francisco and their impact in its neighborhoods. The increase in fatal overdoses from
 19 prescription opioids has been widely publicized for years. San Francisco, in particular, has faced a
 20 spike in fatal drug overdoses, many of which are attributable to prescription opioids either directly or
 21 because someone who started on prescription opioids transitioned to illegal opioids. The CDC
 22 estimates that for every opioid-related death, there are 733 non-medical users. Applying that
 23 estimate in San Francisco, it is likely that around 10% of the City's residents engaged in non-medical
 24

25
 26 ²⁶ See, e.g., Administrative Memorandum Agreement Between the U.S. Department of Justice and
 27 Mallinckrodt at 5 (dated July 10, 2017) (acknowledging that "[a]s part of their business model
 28 Mallinckrodt collects transaction information, referred to as chargeback data, from their direct
 customers (distributors)").

1 opioid use each year during the opioid crisis. Defendants thus had every reason to believe that
 2 illegal diversion was occurring in San Francisco.

3 52. Indeed, tens of thousands of San Francisco residents inject drugs annually, a number
 4 that increased in correlation with the opioids crisis. As the San Francisco Department of Public
 5 Health (“SFPDH”) wrote in its 2018 annual report regarding substance use in the City, *Substance*
 6 *Use Trends in San Francisco Through 2018*:

8 From 2006 through 2016, during the national opioid crisis, San Francisco saw
 9 an increase in the estimated number of people who inject drugs from fewer than
 10 10,000 to nearly 25,000 persons. Despite this change, we did not see an increase in
 11 overall overdose mortality from opioids, cocaine, or methamphetamine during that
 12 period. We attribute this success to the efforts made by San Francisco residents and
 service providers. For example, we know from research with the Drug Overdose
 Prevention and Education (DOPE) Project, that people who use heroin or
 methamphetamine are also the most likely people to use naloxone to reverse an
 overdose, supporting their community by saving lives.

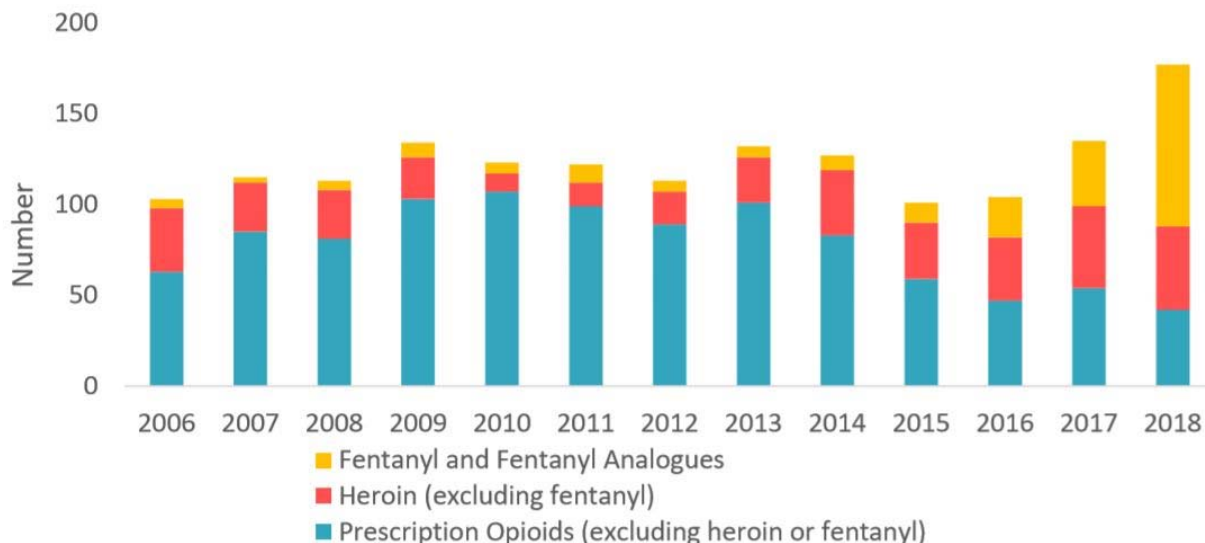
13 Unfortunately, San Francisco did witness an increase in overdose deaths in
 14 2018, which can be attributed to a rise in fentanyl overdose.²⁷

15 53. While opioid prescriptions have finally started to subside, the number of opioid
 16 overdose deaths in San Francisco has nevertheless spiked over the past two years, as reflected in the
 17 following chart:²⁸

26 ²⁷ Dr. Phillip O. Coffin, et al., *Substance Use Trends in San Francisco Through 2018*, at 3 (Dec.
 27 2019), <https://ndews.umd.edu/sites/ndews.umd.edu/files/San-Francisco-Substance-Use-2019-Annual-Report-Trends-Through-2018.pdf>.

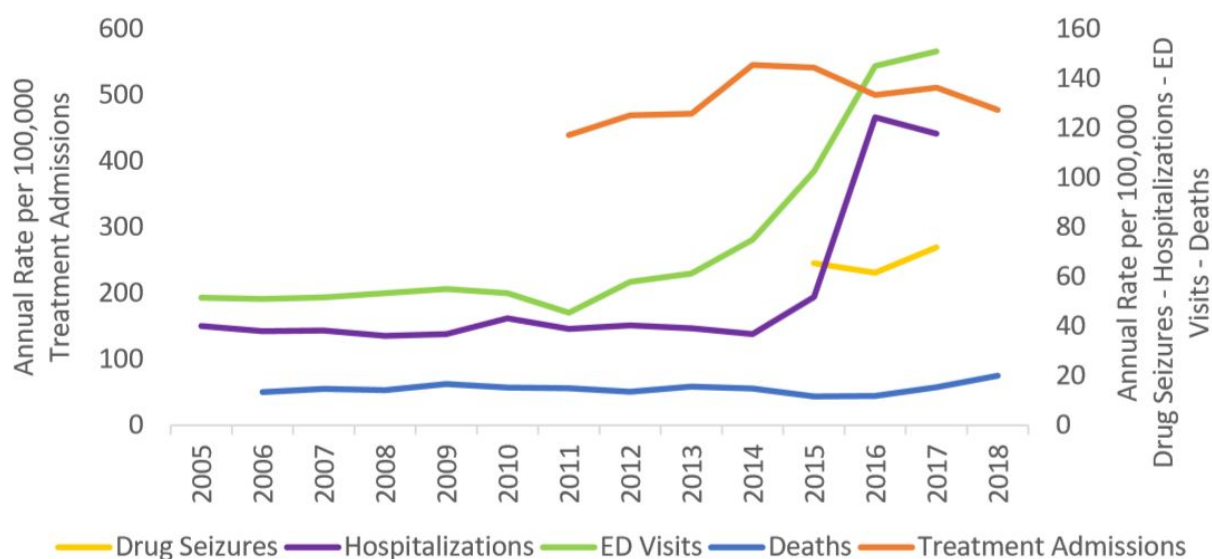
28 ²⁸ *Id.* at 10.

Figure 6: Number of Opioid Overdose Deaths by Mutually Exclusive Opioid Type in CCSF, 2006–2018



54. Other indicia of opioid morbidity also increased around the same time. While emergency department visits, hospitalizations, and overdose deaths had been largely consistent between 2005 and 2013, they increased, in turn, starting in 2014 (emergency department visits), 2015 (hospitalizations), and, as reflected in the chart in the paragraph above, 2018 (deaths):²⁹

Figure 5: Rate of Opioid Use Health Indicators in CCSF, 2005–2018



²⁹ *Id.* at 9.

55. Other indicia provide different insight into the effect of the opioid crisis on San Francisco. For example, thousands more may have died annually but for the provision of naloxone. In 2018, San Francisco paramedics administered naloxone to 1,647 people, up from 980 two years earlier.³⁰ And in 2017, San Francisco laypeople, mostly drug users themselves, administered 1,658 doses of naloxone to reverse overdoses.³¹ It is therefore entirely reasonable to assume there would have been thousands more opioid overdose deaths in San Francisco in the past decade but for the City's recognition of the need to purchase and distribute naloxone widely.

56. Indeed, the reason some San Franciscans can be witnessed shooting up on the street is not because they are homeless addicts, but rather because it is safer to "fix" on the streets due to the prevalence of naloxone in the community in the event of an overdose. According to one community health worker: "If you're in Downtown S.F. and you ask for Narcan, five people will come running."³² A San Francisco resident drug user shared her experience: "I've used Narcan a lot with other people. . . . In the last three months, I've been around 12 overdoses. Seven of them I Narcaned myself. Two of them passed away. But a lot of them are still here because I had it."³³

57. Other widespread effects on San Francisco provide more nuanced insight into the pervasiveness of the opioid crisis. To cite but a few examples, the City was required to replace toilet grinders at the main library because drug users routinely flush needles down the toilet, ruining the grinder pumps, and library staff have been stuck by needles in the stacks. The Fire Department, which provides the majority of the City's emergency medical services, has added specialized units to

³⁰ Brian Rinker, *Drug users, equipped with naloxone, are helping to reverse overdoses in San Francisco*, ABC News (June 14, 2019), <https://abcnews.go.com/Health/drug-users-equipped-naloxone-helping-reverse-overdoses-san/story?id=63696298>.

³¹ *Id.*

³² Nuala Sawyer Bishari, *A Radical Reversal*, SF Weekly (Apr. 4, 2018), <https://www.sfweekly.com/topstories/a-radical-reversal/>.

³³ *Id.*

1 handle frequent 911 callers, many of whom are drug addicts. The Sheriff's Department has had to
 2 purchase specialized mail screening equipment – at a cost of \$250,000 per unit – to detect fentanyl
 3 being sent into the jails and obtain specialized training and materials for handling and disposal of the
 4 drug. Again, these are but a few examples of the many ways in which the opioid crisis has affected
 5 San Francisco and its residents.
 6

7 58. The costs of this ongoing human tragedy cannot be calculated or adequately
 8 compensated. But the financial costs that are already known are staggering. In 2017, then-Mayor
 9 Edwin Lee unveiled his proposed budget for San Francisco for 2017-2018 and 2018-2019, which
 10 included new investments specifically targeted at addressing “[t]he surge of opiate abuse and
 11 addiction.” For 2017-2018, those specific line items, which did not include numerous other services
 12 required to address the opioid crisis’s effects on the City and its residents, comprised \$18.8 million.
 13 For 2018-2019, those line items comprised \$23.2 million.³⁴ Though these line items are aimed at
 14 remediating the opioid crisis, they are constrained by other budgetary needs and are woefully
 15 insufficient to truly abate the ongoing harms caused by Defendants.
 16

17 59. As explained above, the Marketing Defendants overcame barriers to the widespread
 18 prescribing of opioids for chronic pain with deceptive messages about the risks and benefits of long-
 19 term opioid use. All of the Defendants compounded these harms by supplying opioids beyond even
 20 what this expanded market could bear, funneling so many opioids into San Francisco for a period of
 21 time that they could only have been delivering opioids for diversion and illicit use. The flood of
 22 opioids into San Francisco as a result of Defendants’ wrongful conduct has devastated these
 23 communities. The effects of Defendants’ wrongful conduct has also proximately caused devastating
 24
 25
 26

27 ³⁴ City & County of San Francisco, California Mayor’s 2017-2018 & 2018-2019 Proposed Budget,
 28 Mayor’s Office of Public Policy and Finance at 15 (June 1, 2017),
https://sfmayor.org/sites/default/files/CSF_Budget_Book_2017_Final_CMYK_LowRes.pdf.

1 ripple effects, in the form of increased heroin, fentanyl, and methamphetamine use, morbidity, and
2 mortality.

3 60. San Francisco has been hard-hit by the opioid crisis and has expended substantial
4 resources to combat its effects. Though San Francisco responded to the crisis swiftly, its efforts
5 have been stymied and overwhelmed in part by the magnitude of the epidemic.
6

7 61. In 2003, San Francisco was the first city in the United States to make naloxone, a life-
8 saving emergency medication that rapidly reverses opioid overdoses, readily available to members of
9 the public through a partnership between the SFPD and a community-based program, the Drug
10 Overdose Prevention and Education Project (“DOPE Project”).³⁵ The goal of the DOPE Project was
11 to integrate overdose prevention education and naloxone distribution into all settings serving people
12 at risk for opioid overdose.³⁶ DOPE Project staff and SFPD medical providers have trained and
13 distributed naloxone at syringe exchange programs, re-entry programs, pain management clinics,
14 methadone maintenance and buprenorphine treatment programs, and single room occupancy
15 hotels.³⁷ These efforts also included training 65 librarians at the public library on naloxone
16 administration in 2017.³⁸ In 2017 alone, the program reported 1,247 overdose reversals – a number
17 that does *not* include naloxone administered by the San Francisco Police Department or paramedics,
18 or naloxone prescribed by medical providers to lay people.³⁹
19
20

21 ³⁵ Laura Enteen et al., *Overdose Prevention and Naloxone Prescription for Opioid Users in San*
22 *Francisco*, 87 J. Urb. Health 931-41 (2010), [http://harmreduction.org/wp-](http://harmreduction.org/wp-content/uploads/2012/02/AJPH-overdose.pdf)
[content/uploads/2012/02/AJPH-overdose.pdf](http://harmreduction.org/wp-content/uploads/2012/02/AJPH-overdose.pdf).

23 ³⁶ *Id.* at 933.

24 ³⁷ *Id.*

25 ³⁸ Ken Miguel, *San Francisco librarians trained to treat drug overdoses*, ABC 7 News (Dec. 27,
26 2017), <https://abc7news.com/health/sf-librarians-trained-to-treat-drug-overdoses/2803729>.

27 ³⁹ Nuala Sawyer Bishari, *A Radical Reversal*, SF Weekly (Apr. 4, 2018),
28 <http://www.sfweekly.com/topstories/a-radical-reversal/>; San Francisco Safe Injection Services Task
Force 2017 Final Report, San Francisco Department of Public Health (Sept. 2017),
<https://www.sfdph.org/dph/files/SIS-taskforce/SIS-Task-Force-Final-Report-2017.pdf>.

62. Despite these efforts, a June 2014 report by Alice A. Gleghorn, Ph.D., County Alcohol and Drug Administrator for SFDPH, noted that indicators of heroin usage in San Francisco had begun to climb starting in 2012: “Heroin indicators have reversed trends from low points reported in 2011 and show growth in treatment admissions, treatment episode consensus, and drug reports among items seized and analyzed by DEA NFLIS laboratories.”⁴⁰ Treatment admissions for heroin, estimated at 1,781 in fiscal year 2010-2011, rose to 1,925 by fiscal year 2012-2013, and the number of treatment episodes primarily related to heroin rose from 3,002 to 3,479 during that same period – more than the treatment episodes caused by any other drug or alcohol in San Francisco.⁴¹

63. While prescriptions of hydrocodone, the most frequently prescribed opioid medication, had declined since 2011, Dr. Gleghorn concluded that “various heroin and prescription opioid indicators, including treatment admission and NFLIS data, showed sustained increases.”⁴² In other words, as hydrocodone prescriptions declined, heroin and other prescription opioid indicators increased.

64. If not for San Francisco’s early leadership in harm reduction efforts surrounding opioid use and abuse, including pioneering the widespread use of Narcan, the City would have seen hundreds more opioid deaths.⁴³ By the end of 2016, there were an estimated 25,000 people injecting drugs in San Francisco – approximately 14,000-17,000 of whom injected heroin.⁴⁴ This represented

⁴⁰ Alice A. Gleghorn, *Drug Abuse Patterns and Trends in the San Francisco Bay Area – Update: June 2014*, Proceedings of the Community Epidemiology Work Group (June 2014), <https://archives.drugabuse.gov/sites/default/files/sanfrancisco2014.pdf>.

⁴¹ *Id.*

⁴² *Id.*

⁴³ Nuala Sawyer Bashari, *A Radical Reversal*, SF Weekly (Apr. 4, 2018), <http://www.sfweekly.com/topstories/a-radical-reversal>.

⁴⁴ Shelly N. Facente et al., *Correction: Estimated hepatitis C prevalence and key population sizes in San Francisco: A foundation for elimination*, PLoS One (Apr. 11, 2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5895024/>; Phillip O. Coffin et al., *Trends in use of* 1ST AMENDED CPT FOR: (1) RICO; (2) PUBLIC NUISANCE; (3) CALIF UCL; AND (4) FALSE

1 an increase of more than 275% from the estimated 9,000 people who injected drugs in San Francisco
2 in 2005.⁴⁵

3 65. More recently still, deaths due to fentanyl overdose have increased exponentially.
4 Twice as many people died of fentanyl overdoses in San Francisco in 2016 as in 2015.⁴⁶ In early
5 2018, the SFDPH unanimously endorsed a task force's recommendation to open what could become
6 the nation's first legal safe-injection site aimed at curbing the opioid epidemic, including the recent
7 spike in fentanyl-related overdoses.⁴⁷

9 66. In sum, despite the City's substantial efforts, opioid overdose deaths in San Francisco
10 have not subsided. They remained constant between 2006 and 2017, at about 100 to 120 overdose
11 deaths per year, with trends showing more deaths caused by prescription opioids than by heroin.⁴⁸ In
12 2009 and 2010, only 13 and 8, respectively, of those deaths each year were from heroin.⁴⁹

14 67. More recently, opioid deaths in San Francisco due to heroin and fentanyl have spiked.
15 Whereas there were 17 such deaths in 2009, and 134 in 2018, officials estimate that that there were

16 *health care and HIV prevention services for persons who inject drugs in San Francisco: Results*
17 *from National HIV Behavioral Surveillance 2005-2012*, Drug and Alcohol Dependence (Jan. 1,
2015), <https://www.ncbi.nlm.nih.gov/pubmed/25468816>.

18 ⁴⁵ Yea-Hung Chen et al., *Estimated Number of People Who Inject Drugs in San Francisco, 2005,*
19 *2009, and 2012*, AIDS Behav. (Dec. 31, 2015), <https://www.ncbi.nlm.nih.gov/pubmed/26721246>.

20 ⁴⁶ Sara Gaiser, *Fentanyl link confirmed in Haight-Ashbury deaths*, San Francisco Examiner (Feb.
21 24, 2018), <http://www.sfexaminer.com/fentanyl-link-confirmed-haight-ashbury-deaths/>.

22 ⁴⁷ Mark Lieber, *Safe injection sites in San Francisco could be first in the US*, CNN (Feb. 7, 2018),
23 <https://www.cnn.com/2018/02/07/health/safe-injection-sites-san-francisco-opioid-epidemic-bn/index.html>; Alex Barasch, *How Safe Injection Facilities Could Reduce Fentanyl Overdoses*, Slate
(Feb. 22, 2018), <https://slate.com/technology/2018/02/how-safe-injection-facilities-could-limit-fentanyl-overdoses.html>.

24 ⁴⁸ San Francisco Safe Injection Services Task Force 2017 Final Report, San Francisco Department
25 of Public Health (Sept. 2017), <https://www.sfdph.org/dph/files/SISTaskforce/SIS-Task-Force-Final-Report-2017.pdf> Appendix B at 5.

26 ⁴⁹ *DAWN ME 2010 County Profiles, San Francisco County, CA*, U.S. Department of Health &
27 Human Services, Substance Abuse and Mental Health Services Administration (2010),
28 <https://www.samhsa.gov/data/sites/default/files/DAWNMEAnnualReport2010/DAWNMEAnnualReport2010/DAWN-ME-AnnualReport2010-009-CA.htm>.

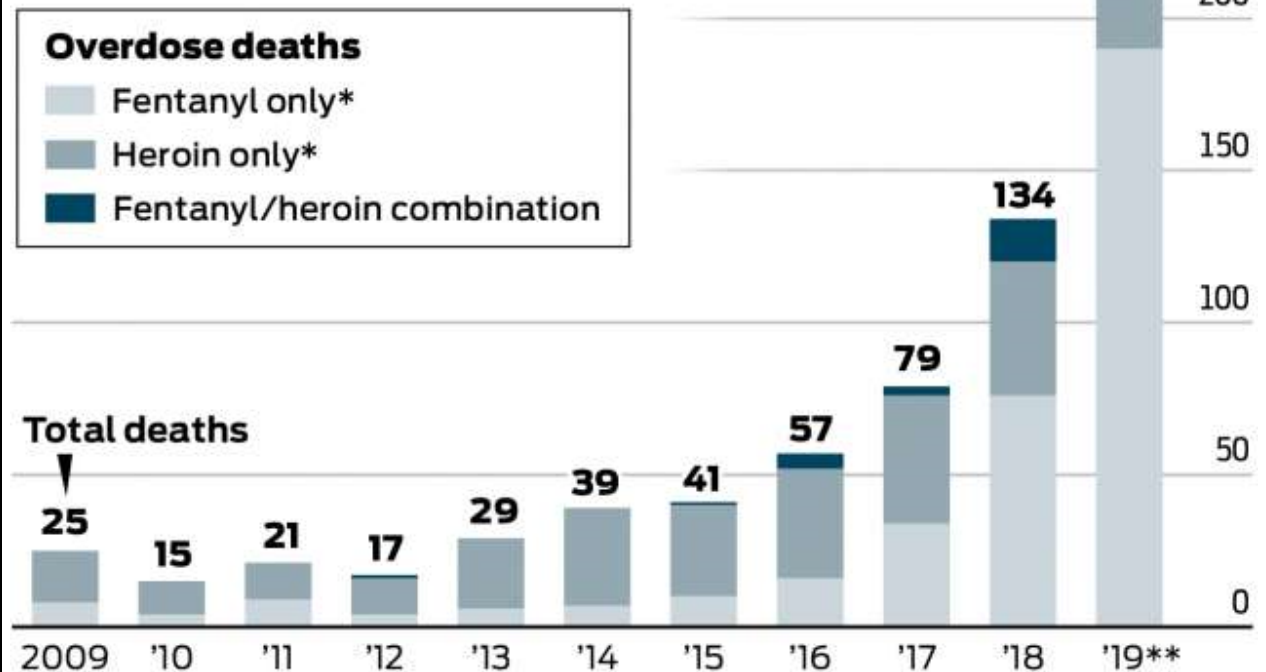
1 290 deaths attributable to fentanyl or heroin in 2019.⁵⁰ Because 80% of new heroin users started
2 with prescription opioid misuse,⁵¹ it follows that many – indeed, most – of the people who died first
3 used prescription opioids before “graduating” to heroin and fentanyl.
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24 ⁵⁰ Evan Sernoffsky, *Fentanyl, heroin overdoses in San Francisco more than double in 2019* (Jan.
25 21, 2020), <https://www.sfchronicle.com/bayarea/article/Fentanyl-heroin-overdoses-in-San-Francisco-more-14993628.php>.

26 ⁵¹ Christopher M. Jones, *Heroin use and heroin use risk behaviors among nonmedical users of*
27 *prescription opioid pain relievers – United States, 2002-2004 and 2008-2010*, 132 (1-2) *Drug and*
28 *Alcohol Dependence* 95-100 (Sept. 1, 2013), [http://www.drugandalcoholdependence.com/article/S0376-8716\(13\)00019-7/fulltext](http://www.drugandalcoholdependence.com/article/S0376-8716(13)00019-7/fulltext).

S.F. fentanyl, heroin deaths

The San Francisco medical examiner's office released new statistics Tuesday showing that the number of people who died from overdoses of fentanyl and/or heroin more than doubled in 2019 compared with 2018.



* Other drugs were possible as the cause of death

** Projections based on typical difference between detections and confirmed accidental overdoses

Source: S.F. medical examiner

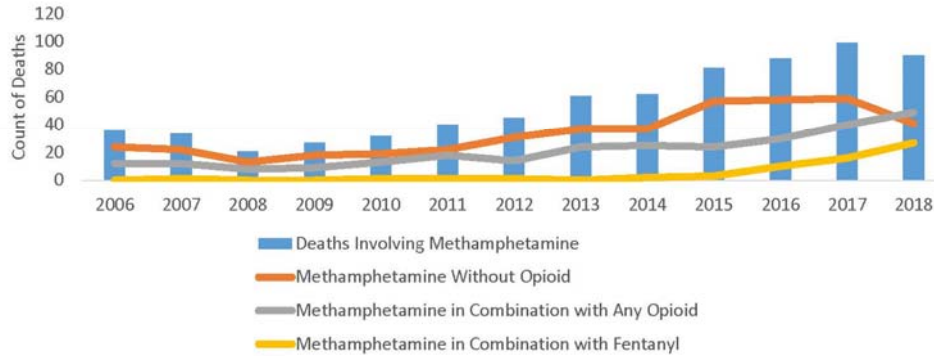
Todd Trumbull / The Chronicle

68. San Francisco has also experienced a recent increase of methamphetamine use and related morbidity and mortality. According to a report about San Francisco as part of the National Drug Early Warning System (a project funded by the National Institute on Drug Abuse), the increase in San Francisco's methamphetamine-related deaths since 2015 is also linked to opioid use.⁵²

⁵² *San Francisco Sentinel Community Site (SCS) Drug Use Patterns and Trends, 2019*, at 4 NDEWS National Drug Early Warning System (Nov. 2019), <https://ndews.umd.edu/sites/ndews.umd.edu/files/SCS-Report-2019-San-Francisco-FINAL.pdf>.

Methamphetamine & Opioid Overlap

Counts of Methamphetamine-Related Deaths in San Francisco by Year and Opioid-Involvement, 2006-2018*



- Prior to 2015, increases in methamphetamine-related deaths were driven by deaths not involving opioids.
- Since 2015, increases in methamphetamine-related deaths have been driven by fentanyl-involvement.

*2018 mortality data are incomplete.

NDEWS San Francisco SCS Drug Use Patterns and Trends, 2019

4

69. All the while, despite some decreases, prescription opioids continue to be dispensed in San Francisco at inflated levels. More than 292,000 opioid prescriptions were written in 2018, more than 330 prescriptions for every 1,000 residents.⁵³

70. On May 17, 2018, then-Mayor Mark Farrell announced that he would invest \$6 million to create a first-in-the-nation program with a dedicated drug addiction street team bringing opioid treatment directly to people experiencing addiction on San Francisco streets.⁵⁴ In the press release, then-Mayor Farrell was quoted as saying: “The opioid crisis plaguing our country is alive

⁵³ *California Opioid Overdose Surveillance Dashboard, San Francisco County Dashboard*, <https://skylab.cdph.ca.gov/ODdash/> (last visited Mar. 13, 2020).

⁵⁴ Press Release, Office of the Mayor, San Francisco, *Mayor Mark Farrell Announces Innovative Program to Fight Opioid Crisis on San Francisco Streets* (May 17, 2018), <https://sfmayor.org/article/mayor-mark-farrell-announces-innovative-program-fight-opioid-crisis-san-francisco-streets>.

1 and visible on the streets of San Francisco. The status quo is simply unacceptable. I am creating this
 2 program to directly address drug addiction on our streets – to meet these individuals where they are
 3 and get them the help they need, and to ensure that our streets remain safe for all our residents.”⁵⁵

4 71. Proactive programs like the ones described above have saved lives, but opioid-related
 5 overdose deaths continue at elevated rates. Moreover, the ongoing toll of the opioid epidemic on
 6 San Francisco and its residents cannot be measured by overdose deaths alone. More users and
 7 addicts in the general population require not only substantially increased public health and safety
 8 expenditures, including the creation of new projects within several City departments to address the
 9 effects of the opioid epidemics, but have also resulted in financial harm suffered by the City in its
 10 role as a business and marketplace participant.

12 JURISDICTION AND VENUE

13 72. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1331 because San
 14 Francisco’s claims under the Racketeer Influenced and Corrupt Organizations Act (“RICO”), 18
 15 U.S.C. §1961 *et seq.*, raise a federal question. It has supplemental jurisdiction over the People’s
 16 state law claims pursuant to 28 U.S.C. §1367 because those claims are so related to the RICO claim
 17 as to form part of the same case or controversy.

19 73. This is a judicial district where Defendants are subject to personal jurisdiction in
 20 accordance with 28 U.S.C. §1391 and Cal. Civ. Proc. Code §410.10, the California long-arm statute.
 21 Defendants Purdue, the Sackler Defendants, Janssen, Endo, Cephalon, Insys, Mallinckrodt, Actavis,
 22 McKesson, Cardinal, AmerisourceBergen, Anda, and Walgreens (as defined below) purposefully
 23 availed themselves of the benefits, profits and privileges deriving from their business activities in
 24 this state. Until April 2019, Defendant McKesson maintained its corporate headquarters in San
 25 Francisco, California.

27 ⁵⁵ *Id.*

74. The non-resident defendants regularly engage in business within the State of California and within this District. Defendants' acts have caused injury to San Francisco. Defendants expect, or should reasonably have expected, those acts to have consequences in the State of California and in San Francisco. Moreover, defendants solicited business within this District, engaged in persistent courses of conduct here and derived substantial revenue from goods used and services rendered in the State of California and this District through interstate commerce.

75. Defendants are regularly engaged in the business of manufacturing, distributing, and dispensing prescription opioids, either directly or indirectly through third-party related entities, in the State of California and, specifically, in San Francisco. Defendants' activities in San Francisco in connection with the manufacture and distribution of prescription opioids were, and are, continuous and systematic, and give rise to the causes of action alleged herein.

76. Venue is proper within this District and this Division pursuant to 28 U.S.C. §1391 and Civil L.R. 3-2(c) because Plaintiffs are located in this District and Division, and a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred here.

INTRADISTRICT ASSIGNMENT

77. Pursuant to Civil Local Rule 3-2(d), this case should be assigned to the San Francisco Division.

PARTIES

II. PLAINTIFFS

78. Plaintiff the City and County of San Francisco ("San Francisco") is one of the 58 counties in the State of California. San Francisco City Attorney Dennis J. Herrera is also authorized to bring claims under California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code §17200 *et seq.*, and California's False Advertising Law ("FAL"), Cal. Bus. & Prof. Code §17500 *et seq.*, on behalf of Plaintiff the People of the State of California. In this lawsuit, the People seek

1 injunctive relief, restitution, and civil penalties for violations of the UCL and FAL and attendant
 2 harms occurring within San Francisco.

3 79. San Francisco City Attorney Dennis J. Herrera is also authorized to bring claims to
 4 abate a public nuisance occurring within San Francisco, pursuant to Cal. Civ. Proc. Code §731, in
 5 the name of the People. In this lawsuit, the People seek abatement of a public nuisance in San
 6 Francisco.
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8 **III. DEFENDANTS**

9 **A. The Marketing Defendants**

10 80. At all relevant times, the Marketing Defendants, each of whom is defined below, have
 11 packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described,
 12 marketed, advertised, promoted, and purported to warn or purported to inform prescribers and users
 13 regarding the benefits and risks associated with the use of prescription opioid drugs. The Marketing
 14 Defendants, at all times, have manufactured and sold prescription opioids without fulfilling their
 15 legal duty to prevent diversion and report suspicious orders.
 16

17 **1. Purdue Entities**

18 81. Defendant Purdue Pharma L.P. (“PPL”) is a limited partnership organized under the
 19 laws of Delaware with its principal place of business in Stamford, Connecticut. None of the PPL’s
 20 partners have citizenship in the State of California.

21 82. Defendant Purdue Pharma Inc. (“PPI”) is a New York corporation with its principal
 22 place of business in Stamford, Connecticut.
 23

24 83. Defendant The Purdue Frederick Company, Inc. (“PFC”) is a New York corporation
 25 with its principal place of business in Stamford, Connecticut.

26 84. Defendant Rhodes Pharmaceuticals L.P. (“Rhodes”) is a Delaware limited partnership
 27 formed in or around 2007 with headquarters located in Coventry, Rhode Island.
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85. PPL, PPI, PFC, and Rhodes and their U.S. Drug Enforcement Administration (“DEA”) registrant subsidiaries and affiliates (collectively, “Purdue”) are engaged in the manufacture, promotion, distribution, and sale of opioids nationally, and in San Francisco, including the following:

Product Name	Chemical Name	Schedule ⁵⁶
OxyContin	Oxycodone hydrochloride, extended release	Schedule II
MS Contin	Morphine sulfate, extended release	Schedule II
Dilaudid	Hydromorphone hydrochloride	Schedule II
Dilaudid-HP	Hydromorphone hydrochloride	Schedule II
Butrans	Buprenorphine	Schedule III
Hysingla ER	Hydrocodone bitrate	Schedule II
Targiniq ER	Oxycodone hydrochloride and naloxone hydrochloride	Schedule II

86. Purdue made thousands of payments to physicians nationwide, including those related to opioids in San Francisco, ostensibly for activities including participating on speakers’ bureaus, providing consulting services, assisting in post-marketing safety surveillance, and other services, but in fact to deceptively promote and maximize the use of opioids.

87. OxyContin is Purdue’s largest-selling opioid. Since 2009, Purdue’s national annual sales of OxyContin have fluctuated between \$2.47 billion and \$3.1 billion, up four-fold from 2006 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (*i.e.*, painkillers). Sales of OxyContin (launched in 1996) went from a mere \$49 million in its first full year on the market to \$1.6 billion in 2002.

⁵⁶ Since passage of the CSA, opioids have been regulated as controlled substances. As controlled substances, they are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the most dangerous. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally had been categorized as Schedule II or Schedule III drugs; hydrocodone and tapentadol were recently reclassified from Schedule III to Schedule II. Schedule II drugs have a high potential for abuse, and may lead to severe psychological or physical dependence. Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high psychological dependence.

1 88. In 2007, Purdue settled criminal and civil charges against it for misbranding
 2 OxyContin and agreed to pay the United States \$635 million – at the time, one of the largest
 3 settlements with a drug company for marketing misconduct. None of this stopped Purdue. In fact,
 4 Purdue continued to create the false perception that opioids were safe and effective for long-term
 5 use, even after being caught, by using unbranded marketing methods to circumvent the system. In
 6 short, Purdue paid the fine when caught and then continued business as usual, deceptively marketing
 7 and selling billions of dollars of opioids each year.

9 89. The action against Purdue is currently stayed.⁵⁷

10 **2. Sackler Defendants**

11 90. Defendant Richard S. Sackler is a natural person residing in Travis County, Texas.
 12 Richard Sackler served as a member of the Board of Directors of Purdue since the 1990s. Richard
 13 Sackler is one of the six inventors listed on the original patent for OxyContin. He began working for
 14 Purdue in the 1970s as an assistant to his father, Raymond Sackler, who served as the president of
 15 the company at that time. Richard Sackler rose through leadership in the subsequent decades,
 16 serving as President of Purdue from 1999 to 2003. He resigned from his role in 2003 over apparent
 17 worry that executive officers of Purdue would be held personally liable for any opioid-related
 18 liabilities.

20 91. Richard Sackler continued to serve as co-chair of Purdue's board with his uncle,
 21 Mortimer D. Sackler, and as chair after the latter's death in 2010. Service on Purdue's very active
 22 board, including Richard Sackler's service as chair, allowed the Sackler family to retain control of
 23 the company regardless of whether they also served as executives.

25 92. During his executive tenure at Purdue and after, Richard Sackler actively participated
 26 in every aspect of the company's opioid business, from invention to marketing to sale. With the

27 ⁵⁷ See *supra* n.1.

1 assistance of his father, Raymond, and his uncle, Mortimer, Richard Sackler introduced OxyContin
2 to the market with one of the largest pharmaceutical advertising campaigns in history. Within five
3 years, OxyContin was earning Purdue \$1 billion a year.

4 93. Further, at all relevant times, Richard Sackler served as trustee of one or more trusts
5 that own and control Purdue. He is the direct or indirect beneficiary of some portion of 25% of the
6 profits earned from the sale of opioids by Purdue.

7 94. Notably, when Richard Sackler spoke at the launch party for OxyContin while
8 serving as Purdue's senior vice president responsible for sales, he instructed the audience to imagine
9 a series of natural disasters: an earthquake, a volcanic eruption, a hurricane, and a blizzard. He said,
10 "the launch of OxyContin Tablets will be followed by a blizzard of prescriptions that will bury the
11 competition. The prescription blizzard will be so deep, dense, and white."

12 95. According to Richard Sackler's publicly disclosed emails, in 1999, when employee
13 Michael Friedman reported to Richard Sackler that Purdue was making more than \$20,000,000 per
14 week, Richard replied immediately, at midnight, that the sales were "not so great." He continued:
15 "After all, if we are to do 900M this year, we should be running at 75M/month. So it looks like this
16 month could be 80 or 90M. Blah, humbug. Yawn. Where was I?" Richard Sackler also personally
17 directed his sales reps not to tell doctors the truth about Purdue's opioids because the truth could hurt
18 sales.

19 96. In or about 2001, Richard Sackler wrote down his solution to the overwhelming
20 evidence of overdose and death: blame and stigmatize people who become addicted to opioids.
21 "[W]e have to hammer on the abusers in every way possible. They are the culprits and the problem.
22 They are reckless criminals." When *TIME* began reporting on OxyContin deaths in 2001, Richard
23 Sackler responded to employee concerns that *TIME*'s coverage of people who lost their lives to
24 OxyContin was not "balanced," and that the deaths were the fault of "the drug addicts," instead of
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1 Purdue. “We intend to stay the course and speak out for people in pain – who far outnumber the
 2 drug addicts abusing our product.” That spring, Purdue executives met with the DEA. A senior
 3 DEA official sat across from Richard Sackler. Before the meeting ended, she leaned over the table
 4 and told Richard: “People are dying. Do you understand that?”⁵⁸

5
 6 97. Richard Sackler also stated in the early 2000s: “‘Abusers aren’t victims; they are the
 7 victimizers’” to an unidentified friend, who responded, “‘Abusers die, well that is the choice they
 8 made, I doubt a single one didn’t know of the risks.’” “If people die because they abuse OxyContin,
 9 ‘then good riddance.’” Richard Sackler further stated, “‘Unfortunately, when I’m ambushed by 60
 10 Minutes, I can’t easily get this concept across Calling drug addicts “scum of the earth” will
 11 guarantee that I become the poster child for liberals.’”⁵⁹

12
 13 98. Defendant Jonathan D. Sackler is a natural person residing in Fairfield County,
 14 Connecticut. He served as a member of the board of directors of Purdue since the 1990s. Jonathan
 15 Sackler served as senior vice president of Purdue starting in or around 2000. Like his brother
 16 Richard Sackler, Jonathan Sackler resigned from his position in or after 2003, due to concerns that
 17 the executive officers of Purdue would be held personally liable for crimes and litigation stemming
 18 from Purdue’s opioid products. He continued to serve on Purdue’s board after his resignation. At all
 19 relevant times, Jonathan Sackler served as trustee of one or more trusts that own and control Purdue.
 20 He is the direct or indirect beneficiary of some portion of 25% of the profits earned from the sale of
 21 opioids by Purdue. Jonathan Sackler regularly attended business meetings and business dinners with
 22 Purdue employees.
 23

24
 25 ⁵⁸ 2001 meeting described in *Pain Killer: A “Wonder” Drug’s Trail of Addiction and Death* by
 26 Barry Meier 158 (Rodale 2003). The DEA official was Laura Nagel, head of the DEA Office of
 Diversion Control.

27 ⁵⁹ Erik Larson & Jeff Feeley, *Purdue’s Richard Sackler Allegedly Called Opioid Addicts*
 28 *‘Victimizers’*, Bloomberg (May 7, 2019), <https://www.bloomberg.com/news/articles/2019-05-07/purdue-s-sackler-allegedly-called-opioid-addicts-victimizers>.

99. Defendant Mortimer D.A. Sackler (“Mortimer D.A. Sackler”) is a natural person residing in New York County, New York. Mortimer D.A. Sackler was previously a board member of Purdue and is the direct or indirect beneficiary of 7.14% of the profits earned from the sale of opioids by Purdue. Mortimer D.A. Sackler participated actively in the management of the opioids business, including in sales and marketing. For example, in 2011, as states were looking for ways to curb opioid prescriptions, Mortimer D.A. Sackler sent an email asking if Purdue could sell a generic version of OxyContin in order to “capture more cost sensitive patients.” In 2016, Mortimer D.A. Sackler was involved in discussions with Richard Sackler and Jonathan Sackler about acquiring a company that used implantable drug pumps to treat opioid addiction.⁶⁰

100. Defendant Kathe A. Sackler is a natural person residing in Fairfield County, Connecticut. She served as a member of the board of directors of Purdue since the 1990s. Kathe Sackler began serving as senior vice president of Purdue in or around 2000. She resigned from her position in or about 2003 due to concerns that the executive officers of Purdue could be held personally liable for crimes and litigation stemming from Purdue’s opioid products. She continued to serve on Purdue’s board. She is the direct or indirect beneficiary of 7.14% of the profits earned from the sale of opioids by Purdue. As a member of the board, Kathe Sackler participated in and directed the affairs of Purdue. She also regularly attended business meetings and business dinners with company employees.

101. In September 2014, Kathe Sackler dialed in to a confidential call about *Project Tango*, which was a secret plan for Purdue to expand into the business of selling drugs to treat opioid addiction. In their now publicly disclosed internal documents, Kathe Sackler and her staff wrote down what Purdue had publicly denied for years: that addictive opioids and opioid addiction are

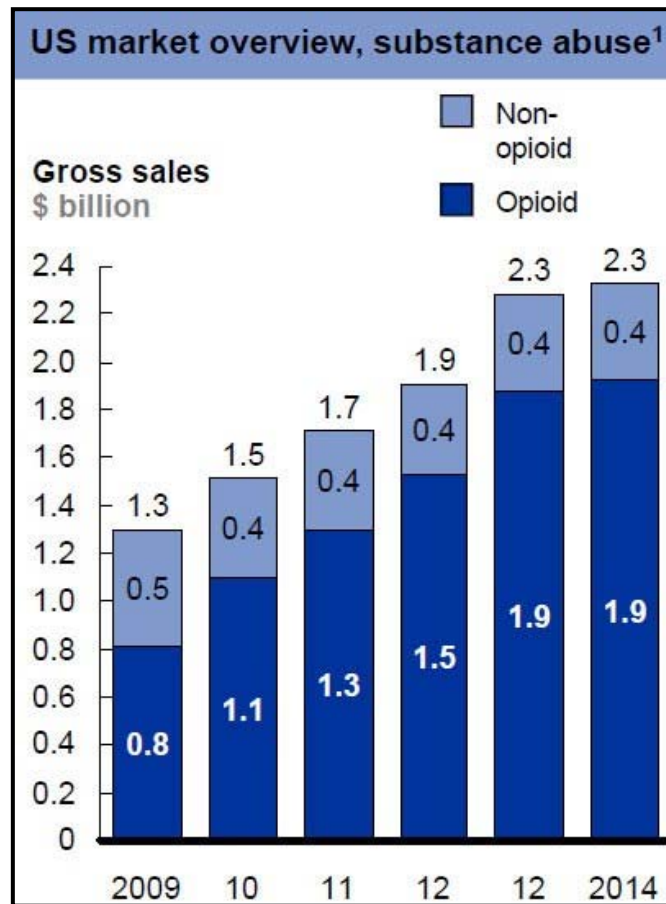
⁶⁰ Danny Hakim, Roni Caryn Rabin & William K. Rashbaum, *Lawsuits Lay Bare Sackler Family’s Role in Opioid Crisis*, The New York Times (Apr. 1, 2019), <https://www.nytimes.com/2019/04/01/health/sacklers-oxycontin-lawsuits.html>.

1 “naturally linked.” They determined that Purdue should expand across “the pain and addiction
 2 spectrum” to become “an end-to-end pain provider.” Purdue illustrated the end-to-end business
 3 model with a picture of a dark hole labeled “Pain treatment” that a patient could fall into – and
 4 “Opioid addiction treatment” waiting at the bottom.



25 102. Kathe Sackler and the *Project Tango* team reviewed their findings that the “market”
 26 of people addicted to opioids, measured coldly in billions of dollars, had doubled from 2009 to 2014.
 27 Kathe Sackler and the staff found that the catastrophe provided an excellent compound annual
 28

growth rate (“CAGR”): “Opioid addiction (other than heroin) has grown by ~20% CAGR from 2000 to 2010.”



103. Kathe Sackler and the staff revealed in their internal documents that Purdue’s tactic of blaming addiction on untrustworthy patients was a lie, admitting the truth is that opioid addiction can happen to anyone who is prescribed opioids:

▪ *“This can happen to any-one – from a 50 year old woman with chronic lower back pain to a 18 year old boy with a sports injury, from the very wealthy to the very poor”*

Purdue’s *Project Tango* patient and clinical rationale.

104. Kathe Sackler and the staff concluded that millions of people who became addicted to opioids were Purdue’s next business opportunity. The staff wrote: “It is an attractive market. Large unmet need for vulnerable, underserved, and stigmatized patient population suffering from substance

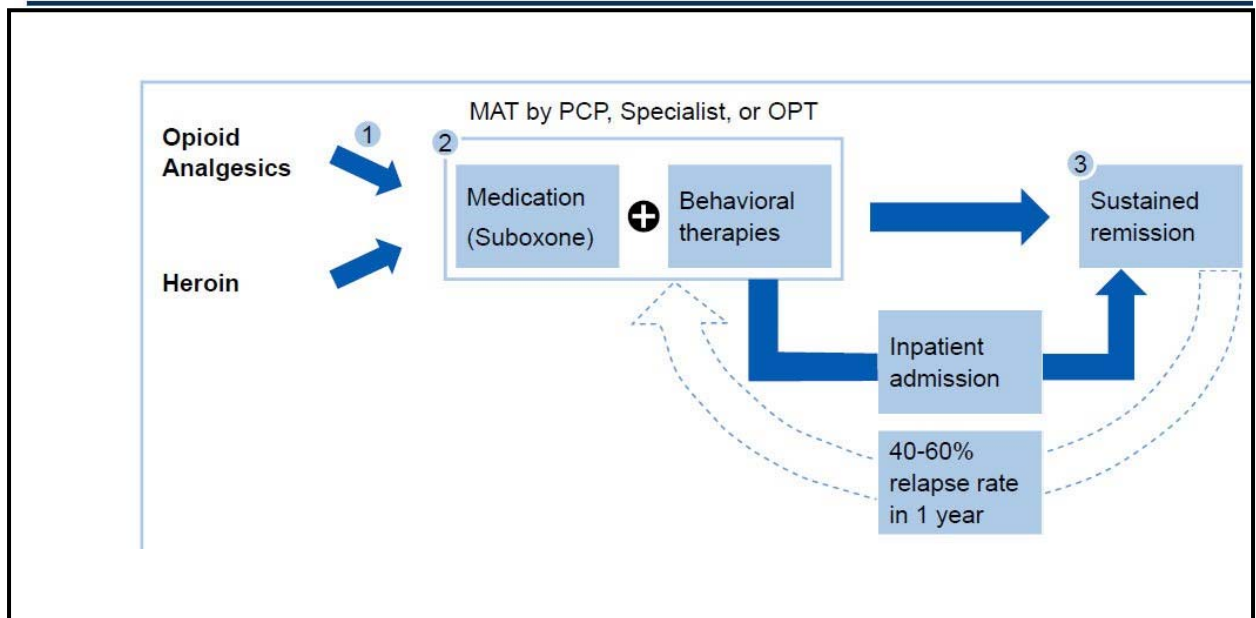
1 abuse, dependence and addiction.” The team identified eight ways that Purdue’s experience getting
2 patients *on* opioids could now be used to sell treatment for opioid addiction.

3 105. Kathe Sackler instructed the staff that *Project Tango* required their “immediate
4 attention.” She pressed the staff to look into reports of children requiring hospitalization after
5 swallowing buprenorphine – the active ingredient in both Purdue’s Butrans opioid and the opioid
6 addiction treatment that Purdue wanted to sell, through *Project Tango*, in a film that melts in one’s
7 mouth. The staff assured Kathe Sackler that children were overdosing on pills, not films, “which is a
8 positive for *Tango*.”
9

10 106. In February 2015, the staff presented Kathe Sackler’s work on *Project Tango* to the
11 board. The plan was for a joint venture controlled by Purdue to sell buprenorphine as addiction
12 medication.
13

14 107. The *Project Tango* team mapped how patients could get addicted to opioids through
15 prescription opioid analgesics such as Purdue’s OxyContin or heroin, and then become consumers of
16 the new company’s buprenorphine. The team noted the opportunity to capture customers: even after
17 patients were done buying buprenorphine the first time, 40%-60% would relapse and need it again.
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Illustrative Patient Flow



108. The next month, *Project Tango* came to an end. Kathe, David, Jonathan, and Mortimer Sackler discussed the discontinuation of the project at their Business Development Committee meeting. But Purdue's and the Sacklers' efforts to sell addictive opioids continued.

109. Defendant Ilene Sackler Lefcourt is a natural person residing in New York County, New York. She served as a member of the board of directors of Purdue since the 1990s. Ilene Sackler Lefcourt served as vice president of Purdue during the initial development and launch of OxyContin. She, too, resigned from her position around 2003 due to concerns of personal liability for executive officers of Purdue for opioid-related crimes and litigation but continued to serve on the board. As a member of the board, Ilene Sackler Lefcourt participated, among other things, in formulating policies related to Purdue's marketing and increasing its sales.

110. Defendant Beverly Sackler is a natural person residing in Fairfield County, Connecticut. She served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

111. Defendant Theresa Sackler is a natural person residing in New York County, New York. She served as a member of the board of directors of Purdue since the 1990s. She is the direct

1 or indirect beneficiary of some portion of the 50% of profits earned by Purdue through the sale of
 2 opioids. As a member of the board, Theresa Sackler has participated in and directed Purdue's public
 3 messaging.

4 112. Defendant David A. Sackler is a natural person residing in New York County, New
 5 York. He served as a member of the board of directors of Purdue since 2012. He also served on the
 6 Business Development Committee of Rhodes and was intimately involved in overseeing and
 7 approving Rhodes' business activities. He is the direct or indirect beneficiary of some portion of
 8 25% of the profits earned by Purdue through the sale of opioids. As a member of the board, David
 9 Sackler has participated in and directed policies designed to increase Purdue's sales.

10 113. Defendant Trust for the Benefit of Members of the Raymond Sackler Family is a trust
 11 for which defendants Beverly Sackler, Richard Sackler and/or Jonathan Sackler are trustees. It is the
 12 50% direct or indirect beneficial owner of Purdue and the Purdue-related entities and the recipient of
 13 50% of the profits from the sale of opioids by Purdue and Purdue-related entities.

14 114. The action against the Sackler Defendants is currently stayed.⁶¹

15 3. Actavis Entities

16 115. Defendant Allergan plc (f/k/a Actavis plc) is a public limited company incorporated
 17 in Ireland with its principal place of business in Dublin, Ireland, and its administrative headquarters
 18 and all executive officers located in Madison, New Jersey. In October 2012, the Actavis Group was
 19 acquired by Watson Pharmaceuticals, Inc. and the combined company changed its name to Actavis,
 20 Inc. as of January 2013, and then to Actavis plc in October 2013. In October 2013, Actavis plc
 21 (n/k/a Allergan plc) acquired Warner Chilcott plc pursuant to a transaction agreement dated May 19,
 22 2013. Actavis plc (n/k/a Allergan plc) was established to facilitate the business combination
 23 between Actavis, Inc. (n/k/a Allergan Finance, LLC) and Warner Chilcott plc. Following the
 24

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 28 ⁶¹ See *supra* n.1.

1 consummation of the October 1, 2013 acquisition, defendant Actavis, Inc. (n/k/a Allergan Finance,
 2 LLC) and Warner Chilcott plc became wholly-owned subsidiaries of Actavis plc (n/k/a Allergan
 3 plc). Pursuant to the transaction, each of Actavis, Inc.’s common shares was converted into one
 4 Actavis plc share. Further, Actavis plc (n/k/a Allergan plc) was the “successor issuer” to Actavis,
 5 Inc. and Warner Chilcott plc. Actavis plc acquired Allergan, Inc. in March 2015, and the combined
 6 company thereafter changed its name to Allergan plc. AbbVie, Inc. (“AbbVie”) is a Delaware
 7 Corporation. On June 25, 2019, AbbVie announced it would acquire Allergan plc in a cash and
 8 stock transaction agreement valued at \$63 billion. As of the filing date of this complaint, the deal
 9 has yet to close. Plaintiffs herein reserve their rights to amend in AbbVie as a successor-in-interest
 10 to Allergan’s liability for the claims alleged in this complaint should that become necessary and
 11 appropriate.
 12

13
 14 116. The transaction that created Actavis plc converted each share of Actavis Inc.’s Class
 15 A common shares into one Actavis plc Ordinary Share. *See City of Chicago v. Purdue Pharma L.P.*,
 16 No. 14 C 4361, 2015 WL 2208423, at *7 (N.D. Ill. May 8, 2015). Actavis Inc. and Actavis plc had
 17 the same corporate headquarters both before and after the merger; Actavis plc had the same website
 18 as Actavis Inc.; and, Actavis plc maintained all of Actavis Inc.’s officers in the same positions. *See*
 19 *id.* Actavis plc’s SEC filings explained that “[r]eferences throughout . . . to “we,” “our,” “us,” the
 20 “Company” or “Actavis” refer” interchangeably to Watson Pharmaceuticals, Inc., Actavis, Inc., and
 21 Actavis plc depending on the date. *See id.* (citations omitted).
 22

23 117. Defendant Allergan Finance, LLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals,
 24 Inc.) is a limited liability company incorporated in Nevada and headquartered in Madison, New
 25 Jersey. Allergan Finance, LLC is a wholly-owned subsidiary of defendant Allergan plc. In 2008,
 26 Actavis, Inc. (n/k/a Allergan Finance, LLC), acquired the opioid Kadian through its subsidiary,
 27 Actavis Elizabeth LLC, which had been the contract manufacturer of Kadian since 2005. Since
 28

1 2008, Kadian’s label has identified the following entities as the manufacturer or distributor of
2 Kadian: Actavis Elizabeth LLC, Actavis Kadian LLC, Actavis Pharma, Inc., and Allergan USA, Inc.
3 Currently, Allergan USA, Inc. is contracted with UPS SCS, Inc. to distribute Kadian on its behalf.

4 118. Defendant Allergan Sales, LLC is incorporated in Delaware and headquartered in
5 Irvine, California. Allergan Sales, LLC is the current New Drug Application (“NDA”) holder for
6 Kadian, and in 2016, Allergan Sales, LLC held the Abbreviated New Drug Applications (“ANDAs”)
7 for Norco. The Norco ANDAs are currently held by non-defendant Allergan Pharmaceuticals
8 International Limited, which is incorporated in Ireland. Allergan Sales, LLC is the wholly-owned
9 subsidiary of Allergan plc.
10

11 119. Defendant Allergan USA, Inc. is incorporated in Delaware and headquartered in
12 Madison, New Jersey. Allergan USA, Inc. is currently responsible for Norco and Kadian sales.
13 Allergan USA, Inc. is a wholly-owned subsidiary of Allergan plc.
14

15 120. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place
16 of business in Corona, California. Watson Laboratories, Inc. was sold to Teva Pharmaceutical
17 Industries Ltd. as part of Allergan plc’s 2016 sale of its generic businesses to Teva. Prior to the sale,
18 Watson Laboratories, Inc. was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC).
19 Between 2000 and 2015, Watson Laboratories, Inc. held the ANDAs for Norco and was the
20 manufacturer of the drug. Watson Laboratories, Inc. was also the ANDA holder of various generic
21 opioids.
22

23 121. Defendant Warner Chilcott Company, LLC is a limited liability company
24 incorporated in Puerto Rico. Since 2015, Warner Chilcott Company, LLC has been the
25 manufacturer of Norco. Warner Chilcott Company, LLC was a subsidiary of Warner Chilcott plc
26 until Warner Chilcott plc became a wholly-owned subsidiary of Allergan plc in 2013. Warner
27
28

1 Chilcott Company LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's
2 2016 sale of its generic businesses to Teva.

3 122. Defendant Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.) is registered to do
4 business with the California Secretary of State as a Delaware corporation with its principal place of
5 business in New Jersey. Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.) was previously
6 responsible for sales of Kadian and Norco. Actavis Pharma, Inc. was sold to Teva Pharmaceutical
7 Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.
8

9 123. Defendant Actavis South Atlantic LLC is a Delaware limited liability company with
10 its principal place of business in Sunrise, Florida. Actavis South Atlantic LLC was listed as the
11 ANDA holder for oxymorphone and fentanyl transdermal. Actavis South Atlantic LLC was sold to
12 Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to
13 Teva.
14

15 124. Defendant Actavis Elizabeth LLC is a Delaware limited liability company with its
16 principal place of business in Elizabeth, New Jersey. From December 19, 2005, until it purchased
17 the medication in December 2008, Actavis Elizabeth LLC served as the contract manufacturer of
18 Kadian for Alpharma. Actavis Elizabeth LLC held the NDA for Kadian from 2008 to 2013. Actavis
19 Elizabeth LLC was also the holder of ANDAs for the following Schedule II opioid products:
20 oxycodone/acetaminophen; homatropine methylbromide/hydrocodone bitartrate; morphine sulfate
21 capsule; morphine sulfate tablet; oxycodone/hydrochloride tablet; oxycodone/ibuprofen; and
22 oxymorphone tablet. Actavis Elizabeth LLC was sold to Teva Pharmaceutical Industries Ltd. as part
23 of Allergan plc's 2016 sale of its generic businesses to Teva.
24

25 125. Defendant Actavis Mid Atlantic LLC is a Delaware limited liability company with its
26 principal place of business in Parsippany, New Jersey. Actavis Mid Atlantic LLC has held the
27 ANDA for homatropine methylbromide/hydrocodone bitartrate. Actavis Mid Atlantic LLC was sold
28

1 to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to
2 Teva.

3 126. Defendant Actavis Totowa LLC is a Delaware limited liability company with its
4 principal place of business in Parsippany, New Jersey. Actavis Totowa LLC has held the ANDAs
5 for the following Schedule II opioid products: oxycodone/acetaminophen; homatropine
6 methylbromide; oxycodone/hydrochloride.
7

8 127. Defendant Actavis LLC is a Delaware limited liability company with its principal
9 place of business in Parsippany, New Jersey. Defendants Actavis South Atlantic LLC, Actavis
10 Elizabeth LLC, Actavis Mid Atlantic LLC, and Actavis Totowa LLC were all direct subsidiaries of
11 Actavis LLC, which was an indirect subsidiary of defendant Watson Laboratories, Inc. Watson
12 Laboratories, Inc., in turn, was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC).
13 Actavis LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of
14 its generic businesses to Teva.
15

16 128. Defendant Actavis Kadian LLC is a Delaware limited liability company with its
17 principal place of business in Morristown, New Jersey. Actavis Kadian LLC has been identified on
18 Kadian's label as a manufacturer or distributor of Kadian. Actavis Kadian LLC was sold to Teva
19 Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.
20

21 129. Defendant Actavis Laboratories UT, Inc. (f/k/a Watson Laboratories, Inc.-Salt Lake
22 City) is a Delaware limited liability company with its principal place of business in Salt Lake City,
23 Utah. Actavis Laboratories UT, Inc. was the Kadian NDA holder from 2013 to 2016 and was listed
24 as the NDA holder for morphine sulfate capsule. Actavis Laboratories UT, Inc. was sold to Teva
25 Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.
26 Prior to the sale, Actavis Laboratories UT, Inc. was a direct subsidiary of Actavis, Inc. (n/k/a
27 Allergan Finance, LLC).
28

130. Defendant Actavis Laboratories FL, Inc. (f/k/a Watson Laboratories, Inc.-Florida) is a Florida limited liability company with its principal place of business in Davie, Florida. Actavis Laboratories FL, Inc. was a Norco ANDA holder in 2015 and was the ANDA holder of the following Schedule II opioid products: hydrocodone/acetaminophen; hydrocodone/ibuprofen; oxycodone/aspirin; and hydromorphone tablet. Actavis Laboratories FL, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva. Prior to the sale, Actavis Laboratories FL, Inc. was a direct subsidiary of Andrx Corporation, which was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC). Andrx Corporation was transferred to Teva as part of the 2016 sale.

131. Each of these defendants and entities currently is or was previously owned by defendant Allergan plc, which uses or used them to market and sell its drugs in the United States. Collectively, these defendants and entities, and their DEA registrant subsidiaries and affiliates that manufacture, promote, distribute, and sell prescription opioids, are referred to as "Actavis."

132. These defendants manufacture or have manufactured the following drugs as well as generic versions of OxyCodone, Kadian, Duragesic, and Opana in the United States:

Product Name	Chemical Name	Schedule
Kadian	Morphine sulfate, extended release	Schedule II
Norco	Hydrocodone bitartate and acetaminophen	Schedule II

4. Cephalon Entities

133. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA was in the business of selling generic opioids, including a generic form of OxyContin from 2005 to 2009. Teva USA is a wholly-owned subsidiary of defendant Teva Pharmaceutical Industries Ltd. ("Teva Ltd."), an Israeli corporation (collectively, "Teva").

134. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. In 2011, Teva Ltd. acquired Cephalon, Inc.

135. Teva USA and Cephalon, Inc. and their DEA registrant subsidiaries and affiliates (collectively, “Cephalon”) work together to manufacture, promote, distribute and sell both brand name and generic versions of opioids in the United States and in San Francisco, including the following:

Product Name	Chemical Name	Schedule
Actiq	Fentanyl citrate	Schedule II
Fentora	Fentanyl buccal	Schedule II

136. From 2000 forward, Cephalon has made thousands of payments to physicians nationwide, including those related to opioids in California, many of whom were not oncologists and did not treat cancer pain, ostensibly for activities including participating on speakers’ bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

5. Janssen Entities

137. Defendant Johnson & Johnson (“J&J”) is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

138. Defendant Janssen Pharmaceuticals, Inc. (“Janssen Pharmaceuticals”) is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly-owned subsidiary of J&J. J&J corresponds with the FDA regarding Janssen’s products. Janssen Pharmaceuticals formerly was known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc.

139. Defendant Noramco, Inc. (“Noramco”) is a Delaware company headquartered in Wilmington, Delaware and was a wholly-owned subsidiary of J&J and its manufacturer of active pharmaceutical ingredients until July 2016, when J&J sold its interests to SK Capital.

140. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. (“OMP”), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

141. Defendant Janssen Pharmaceutica, Inc. (“Janssen Pharmaceutica”), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

142. J&J, Janssen Pharmaceuticals, Noramco, OMP, and Janssen Pharmaceutica and their DEA registrant subsidiaries and affiliates (collectively, “Janssen”) are or have been engaged in the manufacture, promotion, distribution, and sale of opioids nationally, and in San Francisco. Among the drugs Janssen manufactures or manufactured are the following:

Product Name	Chemical Name	Schedule
Duragesic	Fentanyl	Schedule II
Nucynta ⁶²	Tapentadol hydrochloride, immediate release	Schedule II
Nucynta ER	Tapentadol hydrochloride, extended release	Schedule II

143. Janssen made thousands of payments to physicians nationwide, including those related to opioids in California, ostensibly for activities including participating on speakers’ bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014. Prior to 2009, Duragesic accounted for at least \$1 billion in annual sales.

⁶² Depomed, Inc. acquired the rights to Nucynta and Nucynta ER from Janssen in 2015.

1 144. Information from the U.S. Department of Justice’s Office of the Inspector General
 2 shows that J&J made payments to prescribers, but does not indicate which drug was being promoted
 3 when J&J made these payments.

4 145. Janssen, like many other companies, has a corporate code of conduct, which clarifies
 5 the organization’s mission, values and principles. Janssen’s employees are required to read,
 6 understand, and follow its Code of Conduct for Health Care Compliance. J&J imposes this code of
 7 conduct on Janssen as a pharmaceutical subsidiary of J&J. Documents posted on J&J’s and
 8 Janssen’s websites confirm J&J’s control of the development and marketing of opioids by Janssen.
 9 Janssen’s website “Ethical Code for the Conduct of Research and Development,” names only J&J
 10 and does not mention Janssen anywhere within the document. The “Ethical Code for the Conduct of
 11 Research and Development” posted on the Janssen website is J&J’s company-wide Ethical Code,
 12 which it requires all of its subsidiaries to follow.

13 146. The “Every Day Health Care Compliance Code of Conduct” is a J&J company-wide
 14 document that describes Janssen as one of the “Pharmaceutical Companies of J&J” and as one of the
 15 “J&J Pharmaceutical Affiliates.” It governs how “[a]ll employees of J&J Pharmaceutical
 16 Affiliates,” including those of Janssen, “market, sell, promote, research, develop, inform and
 17 advertise J&J Pharmaceutical Affiliates’ products.” All Janssen officers, directors, employees, and
 18 sales associates must certify that they have “read, understood and will abide by” the code. The code
 19 governs all of the forms of marketing at issue in this case.⁶³

20 6. Endo Entities

21 147. Defendant Endo Health Solutions Inc. (“EHS”) is a Delaware corporation with its
 22 principal place of business in Malvern, Pennsylvania.

23
 24
 25
 26
 27 ⁶³ *Every Day Health Care Compliance – Janssen Pharmaceuticals, Inc.*,
 28 <https://www.yumpu.com/en/document/view/5535548/every-day-health-care-compliance-janssen-pharmaceuticals-inc> (last visited Mar. 12, 2020).

148. Defendant Endo Pharmaceuticals, Inc. (“EPI”) is a wholly-owned subsidiary of EHS and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

149. Defendant Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is a wholly-owned subsidiary of defendant Par Pharmaceutical Companies, Inc. (f/k/a Par Pharmaceutical Holdings, Inc.). Defendant Par Pharmaceutical Companies, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. are referred to collectively as “Par Pharmaceutical.” Par Pharmaceutical was acquired by defendant Endo International plc (“Endo Int’l”) in September 2015 and is an operating company of Endo International plc. EHS, EPI, Par Pharmaceutical, and Endo Int’l and their DEA registrant subsidiaries and affiliates (collectively, “Endo”) manufacture opioids sold nationally and in San Francisco. Among the drugs Endo manufactures or manufactured are the following:

Product Name	Chemical Name	Schedule
Opana ER	Oxymorphone hydrochloride, extended release	Schedule II
Opana	Oxymorphone hydrochloride	Schedule II
Percodan	Oxymorphone hydrochloride and aspirin	Schedule II
Percocet	Oxymorphone hydrochloride and acetaminophen	Schedule II
Generic	Oxycodone	Schedule II
Generic	Oxymorphone	Schedule II
Generic	Hydromorphone	Schedule II
Generic	Hydrocodone	Schedule II

150. Endo made thousands of payments to physicians nationwide, including those related to opioids in California, ostensibly for activities including participating on speakers’ bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

151. Opioids made up roughly \$403 million of Endo's overall revenues of \$3 billion in 2012, accounting for over 10% of Endo's total revenue; Opana ER yielded revenue of \$1.15 billion from 2010 to 2013. Endo also manufactures and sells generic opioids, both directly and through its subsidiaries, Par Pharmaceutical and Qualitest Pharmaceuticals, Inc., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

152. The FDA requested that Endo remove Opana ER from the market in June 2017. The FDA relied on post-marketing data in reaching its conclusion based on risk of abuse.

7. Insys Therapeutics, Inc.

153. Insys Therapeutics, Inc. is a Delaware corporation with its principal place of business in Chandler, Arizona. Insys's principal product and source of revenue is Subsys:

Product Name	Chemical Name	Schedule
Subsys	Fentanyl	Schedule II

154. Insys made thousands of payments to physicians nationwide, including those related to opioids in California, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

155. Subsys is a transmucosal immediate-release formulation ("TIRF") of fentanyl, contained in a single-dose spray device intended for oral under-the-tongue administration. Subsys was approved by the FDA solely for the treatment of breakthrough cancer pain.

156. In 2016, Insys made approximately \$330 million in net revenue from Subsys. Insys promotes, sells, and distributes Subsys throughout the United States, and in San Francisco.

157. Insys's founder and owner was recently arrested and charged, along with other Insys executives, with multiple felonies in connection with an alleged conspiracy to bribe practitioners to

1 prescribe Subsys and defraud insurance companies. Other Insys executives and managers were
2 previously indicted.

3 158. The action against Insys is currently stayed.⁶⁴

4 **8. Mallinckrodt Entities**

5 159. Defendant Mallinckrodt plc is an Irish public limited company with its headquarters
6 in Staines-Upon-Thames, Surrey, United Kingdom. Mallinckrodt plc was incorporated in January
7 2013 for the purpose of holding the pharmaceuticals business of Covidien plc, which was fully
8 transferred to Mallinckrodt plc in June of that year. Mallinckrodt plc also operates under the
9 registered business name Mallinckrodt Pharmaceuticals, with its U.S. headquarters in Hazelwood,
10 Missouri. Defendant Mallinckrodt LLC is a Delaware corporation with its headquarters in
11 Hazelwood, Missouri. Defendant SpecGx LLC is a Delaware limited liability company with its
12 headquarters in Clayton, Missouri, and is a wholly-owned subsidiary of Mallinckrodt plc.
13 Mallinckrodt plc, Mallinckrodt LLC, and SpecGx LLC and their DEA registrant subsidiaries and
14 affiliates (together, "Mallinckrodt") manufacture, market, sell and distribute pharmaceutical drugs
15 throughout the United States, and in San Francisco. Mallinckrodt is the largest U.S. supplier of
16 opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United
17 States, based on prescriptions.

20 160. Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is
21 extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone,
22 which is oxycodone, sold in 15 and 30 mg dosage strengths. In 2009, Mallinckrodt Inc., a subsidiary
23 of Covidien plc, acquired the U.S. rights to Exalgo. The FDA approved Exalgo for treatment of
24 chronic pain in 2012. Mallinckrodt further expanded its branded opioid portfolio in 2012 by
25 purchasing Roxicodone from Xanodyne Pharmaceuticals. In addition, Mallinckrodt developed
26

27 ⁶⁴ See *supra* n.2.

Xartemis XR, an extended-release combination of oxycodone and acetaminophen, which the FDA approved in March 2014, and which Mallinckrodt has since discontinued. Mallinckrodt promoted its branded opioid products with its own direct sales force.

161. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. Mallinckrodt estimated that in 2015 it received approximately 25% of the DEA's entire annual quota for controlled substances that it manufactures. Mallinckrodt also estimated, based on IMS Health data for the same period, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.

162. Mallinckrodt operates a vertically integrated business in the United States: (1) importing raw opioid materials, (2) manufacturing generic opioid products, primarily at its facility in Hobart, New York, and (3) marketing and selling its products to drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers that have mail-order pharmacies, and hospital buying groups.

163. Among the drugs Mallinckrodt manufactures or has manufactured are the following:

Product Name	Chemical Name	Schedule
Exalgo	Hydromorphone hydrochloride, extended release	Schedule II
Roxicodone	Oxycodone hydrochloride	Schedule II
Xartemis XR	Oxycodone hydrochloride and acetaminophen	Schedule II
Methadose	Methadone hydrochloride	Schedule II
Generic	Morphine sulfate, extended release	Schedule II
Generic	Morphine sulfate oral solution	Schedule II
Generic	Fentanyl transdermal system	Schedule II
Generic	Oral transmucosal fentanyl citrate	Schedule II
Generic	Oxycodone and acetaminophen	Schedule II
Generic	Hydrocodone bitartrate and acetaminophen	Schedule II
Generic	Hydromorphone hydrochloride	Schedule II

Product Name	Chemical Name	Schedule
Generic	Hydromorphone hydrochloride, extended release	Schedule II
Generic	Naltrexone hydrochloride	Schedule II
Generic	Oxymorphone hydrochloride	Schedule II
Generic	Methadone hydrochloride	Schedule II
Generic	Oxycodone hydrochloride	Schedule II
Generic	Buprenorphine and naloxone	Schedule II

164. Mallinckrodt made thousands of payments to physicians nationwide, including those related to opioids in California, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

165. Collectively, Purdue, Actavis, Cephalon, Janssen, Endo, Insys, Mallinckrodt and the Sackler Defendants are referred to as "Marketing Defendants."⁶⁵

B. The Distributor Defendants

166. The Distributor Defendants (AmerisourceBergen, Anda, Cardinal, McKesson, and Walgreens) are defined below. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Defendants universally failed to comply with federal and/or state law. The Distributor Defendants are engaged in "wholesale distribution," as defined under state and federal law. Plaintiffs allege the unlawful conduct by the Distributor Defendants is a substantial cause for the volume of prescription opioids plaguing San Francisco.

⁶⁵ Together, Purdue, Cephalon, Janssen, Endo, and Mallinckrodt are also sometimes referred to as "RICO Marketing Defendants."

1 **1. AmerisourceBergen Drug Corporation**

2 167. AmerisourceBergen Drug Corporation (“AmerisourceBergen”), through its various
3 DEA registrant subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that
4 distributes opioids throughout the country. AmerisourceBergen is the eleventh largest company by
5 revenue in the United States, with annual revenue of \$147 billion in 2016. AmerisourceBergen’s
6 principal place of business is located in Chesterbrook, Pennsylvania, and it is incorporated in
7 Delaware.
8

9 **2. Anda, Inc.**

10 168. Defendant Anda, Inc., (“Anda”) through its various DEA registrant subsidiaries and
11 affiliated entities, including but not limited to, Anda Pharmaceuticals, Inc., is the fourth largest
12 distributor of generic pharmaceuticals in the United States. Anda is a Florida corporation with its
13 principal offices located in Weston, Florida. In October 2016, defendant Teva acquired Anda from
14 Allergan plc (*i.e.*, defendant Actavis) for \$500 million in cash. At all times relevant to this
15 complaint, Anda distributed prescription opioids throughout the United States, including in
16 California and San Francisco specifically.
17

18 **3. Cardinal Health, Inc.**

19 169. Cardinal Health, Inc. (“Cardinal”) describes itself as a “global, integrated healthcare
20 services and products company,” and is the fifteenth largest company by revenue in the United
21 States, with annual revenue of \$121 billion in 2016. Through its various DEA registrant subsidiaries
22 and affiliated entities, Cardinal distributes pharmaceutical drugs, including opioids, throughout the
23 country. Cardinal is an Ohio corporation and is headquartered in Dublin, Ohio. Based on defendant
24 Cardinal’s own estimates, one of every six pharmaceutical products dispensed to United States
25 patients travels through the Cardinal Health network.
26
27
28

1 **4. McKesson Corporation**

2 170. McKesson Corporation (“McKesson”) is fifth on the list of Fortune 500 companies,
3 ranking immediately after Apple and ExxonMobil, with annual revenue of \$191 billion in 2016.
4 McKesson, through its various DEA registrant subsidiaries and affiliated entities, is a wholesaler of
5 pharmaceutical drugs that distributes opioids throughout the country. McKesson is incorporated in
6 Delaware and had its principal place of business in San Francisco, California until April 1, 2019,
7 when it relocated to Las Colinas, Texas.

8
9 171. In January 2017, McKesson paid a record \$150 million to resolve an investigation by
10 the U.S. Department of Justice (“DOJ”) for failing to report suspicious orders of certain drugs,
11 including opioids. In addition to the monetary penalty, the DOJ required McKesson to suspend sales
12 of controlled substances from distribution centers in Ohio, Florida, Michigan and Colorado. The
13 DOJ described these “staged suspensions” as “among the most severe sanctions ever agreed to by a
14 [DEA] registered distributor.”
15

16 **5. Walgreen Co.**

17 172. Defendant Walgreen Co. (“Walgreens”) is an Illinois corporation with its principal
18 place of business in Deerfield, Illinois. Walgreens, through its various DEA-registered affiliated
19 entities, conducted business throughout the United States, including in San Francisco, as a licensed
20 wholesale distributor through mid-2014.

21 173. Additionally, at all relevant times, Walgreens conducted business as a dispenser of
22 opioids through its large network of retail pharmacies throughout the United States, including in San
23 Francisco specifically.
24

25 **C. Agency and Authority**

26 174. All of the actions described in this complaint are part of, and in furtherance of, the
27 unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants’ officers,
28 agents, employees, or other representatives while actively engaged in the management of

1 Defendants' affairs within the course and scope of their duties and employment, and/or with
2 Defendants' actual, apparent, and/or ostensible authority.

3 **FACTUAL ALLEGATIONS**

4 **IV. FACTS COMMON TO ALL CLAIMS**

5 **A. Opioids and Their Effects**

6 175. The term "opioid" refers to a class of drugs that bind with opioid receptors in the
7 brain and includes natural, synthetic, and semi-synthetic opioids. Natural opioids are derived from
8 the opium poppy. Generally used to treat pain, opioids produce multiple effects on the human body,
9 the most significant of which are analgesia, euphoria, and respiratory depression.

10
11 176. The medicinal properties of opioids – as well as their potential for abuse and
12 addiction – have been recognized for millennia. The opium poppy contains various opium alkaloids,
13 three of which are used in the pharmaceutical industry today: morphine, codeine, and thebaine.
14 Early use of opium in Western medicine was a tincture of opium and alcohol called laudanum, which
15 contains all of the opium alkaloids and is still available by prescription today. Chemists first isolated
16 the morphine and codeine alkaloids in the early 1800s.

17
18 177. In 1827, the pharmaceutical company Merck began large-scale production and
19 commercial marketing of morphine. During the American Civil War, field medics commonly used
20 morphine, laudanum, and opium pills to treat the wounded, and many veterans were left with
21 morphine addictions. By 1900, an estimated 300,000 people were addicted to opioids in the United
22 States, and many doctors prescribed opioids solely to prevent their patients from suffering
23 withdrawal symptoms. The nation's first Opium Commissioner, Hamilton Wright, remarked in
24 1911: "The habit has this nation in its grip to an astonishing extent. . . . Our prisons and our
25 hospitals are full of victims of it, it has robbed ten thousand businessmen of moral sense and made
26
27
28

1 them beasts who prey upon their fellows . . . it has become one of the most fertile causes of
 2 unhappiness and sin in the United States.”⁶⁶

3 178. Pharmaceutical companies tried to develop substitutes for opium and morphine that
 4 would provide the same analgesic effects without the addictive properties. In 1898, Bayer
 5 Pharmaceutical Company began marketing diacetylmorphine (obtained from acetylation of
 6 morphine) under the trade name “Heroin.” Bayer advertised heroin as a non-addictive cough and
 7 cold remedy suitable for children, but as its addictive nature became clear, heroin distribution in the
 8 United States was limited to prescription only in 1914 and then banned altogether a decade later.
 9

10 179. Although heroin and opium became classified as illicit drugs, there is little difference
 11 between them and prescription opioids. Prescription opioids are synthesized from the same plant as
 12 heroin, have similar molecular structures, and bind to the same receptors in the human brain.
 13

14 180. Due to concerns about their addictive properties, since 1970, prescription opioids
 15 have usually been regulated at the federal level as Schedule II controlled substances by the DEA.

16 181. Throughout the twentieth century, pharmaceutical companies continued to develop
 17 prescription opioids like Percodan, Percocet, and Vicodin, but these opioids were generally produced
 18 in combination with other drugs, with relatively low opioid content.

19 182. In contrast, OxyContin, the product whose launch in 1996 ushered in the modern
 20 opioid epidemic, is pure oxycodone. Purdue initially made it available in the following strengths: 10
 21 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, and 160 mg. The weakest OxyContin delivers as
 22 much narcotic as the strongest Percocet, and some OxyContin tablets delivered sixteen times that.
 23

24 183. Medical professionals describe the strength of various opioids in terms of morphine
 25 milligram equivalents (“MME”). According to the CDC, doses at or above 50 MME/day double the

26 ⁶⁶ Nick Miroff, *From Teddy Roosevelt to Trump: How Drug Companies Triggered an Opioid*
 27 *Crisis a Century Ago*, The Wash. Post (Oct. 17, 2017), https://www.washingtonpost.com/news/retropolis/wp/2017/09/29/the-greatest-drug-fiends-in-the-world-an-american-opioid-crisis-in-1908/?utm_term=.7832633fd7ca.
 28

1 risk of overdose compared to 20 MME/day, and one study found that patients who died of opioid
2 overdose were prescribed an average of 98 MME/day.

3 184. Different opioids provide varying levels of MMEs. For example, just 33 mg of
4 oxycodone provides 50 MME. Thus, at OxyContin's twice-daily dosing, the 50 MME/day threshold
5 is nearly reached by a prescription of 15 mg twice daily. One 160 mg tablet of OxyContin, which
6 Purdue took off the market in 2001, delivered 240 MME.

8 185. The wide variation in the MME strength of prescription opioids renders misleading
9 any effort to capture "market share" by the number of pills or prescriptions attributed to Purdue or
10 other manufacturers. Purdue, in particular, focuses its business on branded, highly potent pills,
11 causing it to be responsible for a significant percent of the total amount of MME in circulation, even
12 though it currently claims to have a small percent of the market share in terms of pills or
13 prescriptions.

15 186. Fentanyl is a synthetic opioid that is 100 times stronger than morphine and 50 times
16 stronger than heroin. First developed in 1959, fentanyl is showing up more and more often in the
17 market for opioids created by the Marketing Defendants' promotion, with particularly lethal
18 consequences.

19 187. The effects of opioids vary by duration. Long-acting opioids, such as Purdue's
20 OxyContin and MS Contin, Janssen's Nucynta ER and Duragesic, Endo's Opana ER, and Actavis's
21 Kadian, are designed to be taken once or twice daily and are purported to provide continuous opioid
22 therapy for, in general, 12 hours. Short-acting opioids, such as Cephalon's Actiq and Fentora, are
23 designed to be taken in addition to long-acting opioids to address "episodic pain" (also referred to as
24 "breakthrough pain") and provide fast-acting, supplemental opioid therapy lasting approximately 4
25 to 6 hours. Still other short-term opioids, such as Insys's Subsys, are designed to be taken in
26 addition to long-acting opioids to specifically address breakthrough cancer pain, excruciating pain
27
28

1 suffered by some patients with end-stage cancer. The Marketing Defendants promoted the idea that
 2 pain should be treated by taking long-acting opioids continuously and supplementing them by also
 3 taking short-acting, rapid-onset opioids for episodic or “breakthrough” pain.

4 188. Patients develop tolerance to the analgesic effect of opioids relatively quickly. As
 5 tolerance increases, a patient typically requires progressively higher doses in order to obtain the
 6 same perceived level of pain reduction. The same is true of the euphoric effects of opioids – the
 7 “high.” However, opioids depress respiration, and at very high doses can and often do arrest
 8 respiration altogether. At higher doses, the effects of withdrawal are more severe. Long-term opioid
 9 use can also cause hyperalgesia, a heightened sensitivity to pain.
 10

11 189. Discontinuing opioids after more than just a few weeks of therapy will cause most
 12 patients to experience withdrawal symptoms. These withdrawal symptoms include severe anxiety,
 13 nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other
 14 serious symptoms, which may persist for months after a complete withdrawal from opioids,
 15 depending on how long the opioids were used.
 16

17 190. As one doctor put it, the widespread long-term use of opioids “was an experiment on
 18 the population of the United States. It wasn’t randomized, it wasn’t controlled, and no data was
 19 collected until they started gathering death statistics.”
 20

21 **B. The Resurgence of Opioid Use in the United States**

22 **1. The Sackler Family Integrated Advertising and Medicine**

23 191. Given the history of opioid abuse in the United States and the medical profession’s
 24 resulting wariness, the commercial success of the Marketing Defendants’ prescription opioids would
 25 not have been possible without a fundamental shift in prescribers’ perception of the risks and
 26 benefits of long-term opioid use.
 27
 28

1 192. As it turned out, Purdue was uniquely positioned to execute just such a maneuver,
 2 thanks to the legacy of a man named Arthur Sackler. The Sackler family is the sole owner of Purdue
 3 and one of the wealthiest families in America, with a net worth of \$13 billion as of 2016. The
 4 company's profits go to Sackler family trusts and entities. Yet the Sacklers have avoided publicly
 5 associating themselves with Purdue, letting others serve as the spokespeople for the company.
 6

7 193. The Sackler brothers – Arthur, Mortimer, and Raymond – purchased a small patent-
 8 medicine company called the Purdue Frederick Company in 1952. It was Arthur Sackler who
 9 created the pharmaceutical advertising industry as we know it, laying the groundwork for the
 10 OxyContin promotion that would make the Sacklers billionaires.

11 194. Arthur Sackler was both a psychiatrist and a marketing executive. He pioneered both
 12 print advertising in medical journals and promotion through physician “education” in the form of
 13 seminars and continuing medical education courses. He also understood the persuasive power of
 14 recommendations from fellow physicians, and did not hesitate to manipulate information when
 15 necessary. For example, one promotional brochure produced by his firm for Pfizer showed business
 16 cards of physicians from various cities as if they were testimonials for the drug, but when a journalist
 17 tried to contact these doctors, he discovered that they did not exist.
 18

19 195. It was Arthur Sackler who, in the 1960s, made Valium into the first \$100-million
 20 drug, so popular it became known as “Mother’s Little Helper.” When Arthur Sackler’s client,
 21 Roche, developed Valium, it already had a similar drug, Librium, another benzodiazepine, on the
 22 market for treatment of anxiety. So Arthur Sackler invented a condition he called “psychic tension”
 23 – essentially stress – and pitched Valium as the solution.⁶⁷ The campaign, for which Arthur Sackler
 24 was compensated based on volume of pills sold, was a remarkable success.
 25

26
 27 ⁶⁷ Barry Meier, *Pain Killer: A “Wonder” Drug’s Trail of Addiction and Death* 201, 202, 204
 28 (Rodale 2003); *see also One Family Reaped Billions From Opioids*, WBUR On Point (Oct. 23,
 2017), <http://www.wbur.org/onpoint/2017/10/23/one-family-reaped-billions-from-opioids>.

1 196. Arthur Sackler created not only the advertising for his clients but also the vehicle to
 2 bring their advertisements to doctors – a biweekly newspaper called the *Medical Tribune*, which was
 3 distributed for free to doctors nationwide. Arthur Sackler also conceived a company now called IMS
 4 Health Holdings Inc., which monitors prescribing practices of every doctor in the United States and
 5 sells this valuable data to pharmaceutical companies like the Marketing Defendants, who utilize it to
 6 target and tailor their sales pitches to individual physicians.

8 2. Purdue and the Development of OxyContin

9 197. After the Sackler brothers acquired the Purdue Frederick Company in 1952, Purdue
 10 sold products ranging from earwax remover to antiseptic and became a profitable business. As an
 11 advertising executive, Arthur Sackler was not involved, on paper at least, in running Purdue, which
 12 would have been a conflict of interest. Raymond Sackler became Purdue's head executive, while
 13 Mortimer D. Sackler ran Purdue's U.K. affiliate.

14 198. In the 1980s, Purdue, through its U.K. affiliate, acquired a Scottish drug producer that
 15 had developed a sustained-release technology suitable for morphine. Purdue marketed this
 16 extended-release morphine as MS Contin, and it quickly became Purdue's bestseller. As the patent
 17 expiration for MS Contin loomed, Purdue searched for a drug to replace it. Around that time,
 18 Raymond's oldest son, Richard Sackler, who was also a trained physician, became more involved in
 19 the management of the company. Richard Sackler had grand ambitions for the company; according
 20 to a long-time Purdue sales representative, "Richard really wanted Purdue to be big – I mean *really*
 21 big."⁶⁸ Richard Sackler believed Purdue should develop another use for its "Contin" timed-release
 22 system.

23 199. In 1990, Purdue's vice president of clinical research, Robert Kaiko, sent a memo to
 24 Richard Sackler and other executives recommending that the company work on a pill containing

25
 26
 27 ⁶⁸ Christopher Glazek, *The Secretive Family Making Billions from the Opioid Crisis*, Esquire (Oct.
 28 16, 2017), <http://www.esquire.com/news-politics/a12775932/sackler-family-oxycontin/>.

1 oxycodone. At the time, oxycodone was perceived as less potent than morphine, largely because it
2 was most commonly prescribed as Percocet, a relatively weak oxycodone-acetaminophen
3 combination pill. MS Contin was not only approaching patent expiration but had always been
4 limited by the stigma associated with morphine. Oxycodone did not have that problem, and what is
5 more, it was sometimes mistakenly called “oxycodine,” which also contributed to the perception of
6 relatively lower potency, because codeine is weaker than morphine. Purdue acknowledged using
7 this to its advantage when it later pled guilty to criminal charges of “misbranding” in 2007, admitting
8 that it was ““well aware of the incorrect view held by many physicians that oxycodone was weaker
9 than morphine”” and ““did not want to do anything “to make physicians think that oxycodone was
10 stronger or equal to morphine” or “to take any steps . . . that would affect the unique position that
11 OxyContin”“ held among physicians.”⁶⁹

12
13
14 200. For Purdue and OxyContin to be “*really big*,”⁷⁰ Purdue needed to both distance its
15 new product from the traditional view of narcotic addiction risk and broaden the drug’s uses beyond
16 cancer pain and hospice care. A marketing memo sent to Purdue’s top sales executives in March
17 1995 recommended that if Purdue could show that the risk of abuse was lower with OxyContin than
18 with traditional immediate-release narcotics, sales would increase. As discussed below, Purdue did
19 not find or generate any such evidence, but this did not stop Purdue from making that claim
20 regardless.

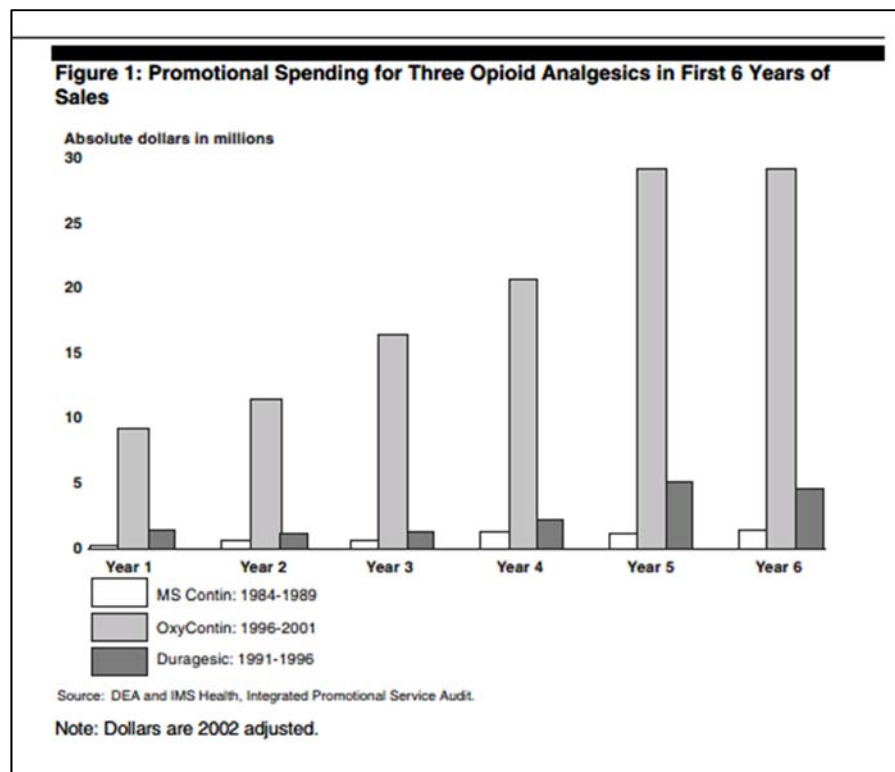
21
22 201. Armed with this and other misrepresentations about the risks and benefits of its new
23 drug, Purdue was able to open an enormous untapped market: patients with non-end-of-life, non-
24 acute, everyday aches and pains. As Dr. J. David Haddox, a Senior Medical Director at Purdue,
25 declared on the *Early Show*, a CBS morning talk program, ““There are 50 million patients in this

26
27 ⁶⁹ *Id.*

28 ⁷⁰ *Id.*

country who have chronic pain that's not being managed appropriately every single day. OxyContin is one of the choices that doctors have available to them to treat that."⁷¹

202. In pursuit of these 50 million potential customers, Purdue poured resources into OxyContin's sales force and advertising, particularly targeting a far broader audience of primary care physicians who treated patients with chronic pain complaints. The graph below shows how promotional spending in the first six years following OxyContin's launch dwarfed Purdue's spending on MS Contin or defendant Janssen's spending on Duragesic.⁷²



203. Prior to Purdue's launch of OxyContin, no drug company had ever promoted such a pure, high-strength Schedule II narcotic to so wide an audience of general practitioners.

⁷¹ Barry Meier, *Pain Killer: A "Wonder" Drug's Trail or Addition and Death* 156 (Rodale 2003).

⁷² U.S. General Accounting Office, *OxyContin Abuse and Diversion and Efforts to Address the Problem*, U.S. General Accounting Office Report to Congressional Requesters, at 22 (Dec. 2003), <http://www.gao.gov/new/items/d04110.pdf>.

204. In the two decades following OxyContin’s launch, Purdue continued to devote substantial resources to its promotional efforts. Nearly *half* of Purdue’s operating expenses in 2015 went to sales and promotion, and more than 80% of its marketing budget of \$241 million was spent on sending sales representatives to meet with prescribers.

205. Purdue has generated estimated sales of more than \$35 billion from opioids since 1996, raking in more than \$3 billion in 2015 alone. Remarkably, its opioid sales continued to climb even after a period of media attention and government inquiries regarding OxyContin abuse in the early 2000s and a criminal investigation culminating in guilty pleas in 2007. Purdue proved itself skilled at evading full responsibility and continuing to sell through the controversy. The company’s annual opioid sales of \$3 billion in 2015 represent a four-fold increase from its 2006 sales of \$800 million.

206. Moreover, in or around November 2007, in the immediate aftermath of the guilty plea by Purdue and its executives regarding the company’s false and misleading marketing of OxyContin, the Sackler Defendants established Rhodes. According to a former senior manager at Purdue, “Rhodes was set up as a ‘landing pad’ for the Sackler family in 2007, to prepare for the possibility that they would need to start afresh following the crisis then engulfing OxyContin.”⁷³

207. The Sacklers’ involvement in Rhodes and its relationship to Purdue was not publicly known until the September 9, 2018 publication of an article in the *Financial Times*. According to the article, “Rhodes has not been publicly connected to the Sackler family before, and their ownership of the company may weaken one of their longstanding defences: that they cannot be held

⁷³ David Crow, *How Purdue’s ‘one-two’ punch fueled the market for opioids*, *Financial Times* (Sept. 9, 2018), <https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6f049d06439c>.

1 responsible for the opioid crisis because Purdue accounts for a small fraction of the overall
2 prescriptions.”⁷⁴

3 208. Despite being registered as a separate company from Purdue, staff from Rhodes and
4 Purdue use the same employee handbook and “little distinction is made internally between the two
5 companies.”⁷⁵

6 209. Rhodes manufactures, markets, sells and distributes generic opioids in San Francisco
7 and nationwide, including hydromorphone, hydrocodone, oxycodone, and morphine sulfate.
8 According to the *Financial Times*, in 2016, Rhodes had a substantially larger share of prescriptions
9 in the U.S. prescription opioid market than Purdue.⁷⁶

10 210. According to public records collected by ProPublica, in 2015 alone, Medicare Part D
11 paid \$4.1 million for claims arising from California physicians’ generic hydromorphone
12 hydrochloride prescriptions, \$102.7 million for claims arising from California physicians’ generic
13 hydrocodone bitartrate/acetaminophen prescriptions, \$38.3 million for claims arising from California
14 physicians’ generic oxycodone/acetaminophen prescriptions, \$34.4 million for claims arising from
15 California physicians’ generic extended release morphine sulfate prescriptions and \$18.1 million for
16 claims arising from California physicians’ generic oxycodone hydrochloride prescriptions.
17

18 211. One might imagine that Richard Sackler’s ambitions have been realized. But in the
19 best tradition of family patriarch Arthur Sackler, Purdue has its eyes on even greater profits. Under
20 the name of Mundipharma, the Sacklers are looking to new markets for their opioids – employing
21 the exact same playbook in South America, China, and India as they did in the United States.
22
23
24

25
26 ⁷⁴ *Id.*

27 ⁷⁵ *Id.*

28 ⁷⁶ *Id.*

212. In May 2017, a dozen members of Congress sent a letter to the World Health Organization warning it of the deceptive practices Purdue was unleashing on the rest of the world through Mundipharma:

We write to warn the international community of the deceptive and dangerous practices of Mundipharma International – an arm of Purdue Pharmaceuticals. The greed and recklessness of one company and its partners helped spark a public health crisis in the United States that will take generations to fully repair. We urge the World Health Organization (WHO) to do everything in its power to avoid allowing the same people to begin a worldwide opioid epidemic. Please learn from our experience and do not allow Mundipharma to carry on Purdue’s deadly legacy on a global stage. . . .

. . . Internal documents revealed in court proceedings now tell us that since the early development of OxyContin, Purdue was aware of the high risk of addiction it carried. Combined with the misleading and aggressive marketing of the drug by its partner, Abbott Laboratories, Purdue began the opioid crisis that has devastated American communities since the end of the 1990s. Today, Mundipharma is using many of the same deceptive and reckless practices to sell OxyContin abroad.

* * *

In response to the growing scrutiny and diminished U.S. sales, the Sacklers have simply moved on. On December 18, the Los Angeles Times published an extremely troubling report detailing how in spite of the scores of lawsuits against Purdue for its role in the U.S. opioid crisis, and tens of thousands of overdose deaths, Mundipharma now aggressively markets OxyContin internationally. In fact, Mundipharma uses many of the same tactics that caused the opioid epidemic to flourish in the U.S., though now in countries with far fewer resources to devote to the fallout.⁷⁷

213. Purdue’s recent pivot to untapped markets – after extracting substantial profits from American communities and leaving local governments to address the devastating and still growing damage the company caused – only serves to underscore that Purdue’s actions have been knowing, intentional, and motivated by profits throughout this entire story.

3. Other Marketing Defendants Leapt at the Opioid Opportunity

214. Purdue created a market for the use of opioids for a range of common aches and pains by misrepresenting the risks and benefits of its opioids, but it was not alone. The other Marketing

⁷⁷ Letter from Members of Congress to Dr. Margaret Chan, Director-General, World Health Organization (May 3, 2017), http://katherineclark.house.gov/_cache/files/a577bd3c-29ec-4bb9-bdba-1ca71c784113/mundipharma-letter-signatures.pdf.

1 Defendants – already manufacturers of prescription opioids – positioned themselves to take
2 advantage of the opportunity Purdue created, developing both branded and generic opioids to
3 compete with OxyContin, while, together with Purdue and each other, misrepresenting the safety and
4 efficacy of their products. These misrepresentations are described in greater detail below.

5
6 215. Endo, which already sold Percocet and Percodan, was the first to submit an
7 application for a generic extended-release oxycodone to compete with OxyContin. At the same
8 time, Endo sought FDA approval for another potent opioid, immediate-release and extended-release
9 oxymorphone, branded as Opana and Opana ER. Oxymorphone, like OxyContin’s active ingredient
10 oxycodone, is not a new drug; it was first synthesized in Germany in 1914 and sold in the United
11 States by Endo beginning in 1959 under the trade name Numorphan. But Numorphan tablets proved
12 highly susceptible to abuse. Called “blues,” after the light blue color of the 10 mg pills, Numorphan
13 provoked, according to some users, a more euphoric high than heroin. As the National Institute on
14 Drug Abuse observed in its 1974 report, ““Drugs and Addict Lifestyle,”” Numorphan was extremely
15 popular among addicts for its quick and sustained effect.⁷⁸ Endo withdrew oral Numorphan from the
16 market in 1979.

17
18 216. Two decades later, however, as communities around the United States were first
19 sounding the alarm about prescription opioids and Purdue executives were being called to testify
20 before Congress about the risks of OxyContin, Endo essentially reached back into its inventory,
21 dusted off a product it had previously shelved after widespread abuse, and pushed it into the
22 marketplace with a new trade name, Opana.

23
24 217. The clinical trials submitted with Endo’s first application for approval of Opana were
25 insufficient to demonstrate efficacy, and some subjects in the trials overdosed and had to be revived
26

27 ⁷⁸ John Fauber & Kristina Fiore, *Abandoned Painkiller Makes a Comeback*, MedPage Today (May
28 10, 2015), <https://www.medpagetoday.com/psychiatry/addictions/51448>.

1 with naloxone. Endo then submitted new “enriched enrollment” clinical trials, in which trial
2 subjects who do not respond to the drug are excluded from the trial, and obtained approval. Endo
3 began marketing Opana and Opana ER in 2006.

4 218. Like Numorphan, Opana ER was highly susceptible to abuse. On June 8, 2017, the
5 FDA sought removal of Opana ER. In its press release, the FDA indicated that “[t]his is the first
6 time the agency has taken steps to remove a currently marketed opioid pain medication from sale
7 due to the public health consequences of abuse.”⁷⁹ On July 6, 2017, Endo agreed to withdraw Opana
8 ER from the market.

10 219. Janssen, which already marketed the Duragesic (fentanyl) patch for severe pain, also
11 joined Purdue in pursuit of the broader chronic pain market. It sought to expand the use of
12 Duragesic through, for example, advertisements proclaiming: “It’s not just for end stage cancer
13 anymore!”⁸⁰ This claim earned Janssen a warning letter from the FDA for representing that
14 Duragesic was “more useful in a broader range of conditions or patients than has been demonstrated
15 by substantial evidence.”⁸¹

17 220. Janssen also developed a new opioid compound called tapentadol in 2009, marketed
18 as Nucynta for the treatment of moderate to severe pain. Janssen launched the extended-release
19 version, Nucynta ER, for treatment of chronic pain in 2011.

21 221. By adding additional opioids or expanding the use of their existing opioid products,
22 the other Marketing Defendants took advantage of the market created by Purdue’s aggressive
23 promotion of OxyContin and reaped enormous profits. For example, Opana ER alone generated

25 ⁷⁹ Press Release, U.S. Food & Drug Admin., *FDA Requests Removal of Opana ER for Risks*
26 *Related to Abuse* (June 8, 2017), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm>.

27 ⁸⁰ Letter from U.S. Food & Drug Admin. to Janssen (Mar. 30, 2000) at 2.

28 ⁸¹ *Id.*

1 more than \$1 billion in revenue for Endo in 2010 and again in 2013. Janssen also passed the
2 \$1 billion mark in sales of Duragesic in 2009.

3 **C. Defendants' Conduct Created an Abatable Public Nuisance**

4 222. As alleged throughout this complaint, Defendants' conduct created a public health
5 crisis and a public nuisance.

6 223. The public nuisance – *i.e.*, the opioid epidemic – created, perpetuated, and maintained
7
8 by Defendants can be abated and further recurrence of such harm and inconvenience can be abated
9 by, *inter alia*, (a) educating prescribers (especially primary care physicians and the most prolific
10 prescribers of opioids) and patients regarding the true risks and benefits of opioids, including the risk
11 of addiction, in order to prevent the next cycle of addiction; (b) providing addiction treatment to
12 patients who are already addicted to opioids; and (c) making naloxone widely available so that
13 overdoses are less frequently fatal.

14 224. It is the manufacturer of a drug that has primary responsibility to assure the safety,
15 efficacy, and appropriateness of a drug's labeling, marketing, and promotion. And all companies in
16 the supply chain of a controlled substance are primarily responsible for ensuring that such drugs are
17 only distributed and dispensed to appropriate patients and not diverted. These responsibilities exist
18 independent of any FDA or DEA regulation to ensure that their products and practices meet both
19 federal and state consumer protection laws and regulations. As registered manufacturers and
20 distributors of controlled substances, Defendants are placed in a position of special trust and
21 responsibility and are uniquely positioned, based on their knowledge of prescribers and orders, to act
22 as a first line of defense.
23
24

25 **D. The Marketing Defendants' Multi-Pronged Scheme to Change**
26 **Prescriber Habits and Public Perception and Increase Demand for**
Opioids

27 225. In order to accomplish the fundamental shift in perception that was key to
28 successfully marketing their opioids, the Marketing Defendants designed and implemented a
1ST AMENDED CPT FOR: (1) RICO; (2) PUBLIC NUISANCE; (3) CALIF UCL; AND (4) FALSE

sophisticated and deceptive marketing strategy. Lacking legitimate scientific research to support their claims, the Marketing Defendants turned to the marketing techniques first pioneered by Arthur Sackler to create a series of misperceptions in the medical community and ultimately reverse the long-settled understanding of the relative risks and benefits of opioids.

226. The Marketing Defendants promoted, and profited from, their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their marketing was false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned the Marketing Defendants of these risks. The Marketing Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term opioid use and that patients were suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC issued pronouncements based on existing medical evidence that conclusively exposed the known falsity of the Marketing Defendants’ misrepresentations.

227. The marketing scheme to increase opioid prescriptions centered around nine categories of misrepresentations, which are discussed in detail below. The Marketing Defendants disseminated these misrepresentations through various channels, including through advertising, sales representatives, purportedly independent organizations the Marketing Defendants funded and controlled, “Front Groups,” so-called industry “Key Opinion Leaders,” and Continuing Medical Education (“CME”) programs as discussed below.

1. The Marketing Defendants Promoted Multiple Falsehoods About Opioids

228. The Marketing Defendants’ misrepresentations fall into the following nine categories:

- (a) The risk of addiction from chronic opioid therapy is low;

1 (b) To the extent there is a risk of addiction, it can be easily identified and
2 managed;

3 (c) Signs of addictive behavior are “pseudoaddiction,” requiring more opioids;

4 (d) Opioid withdrawal can be avoided by tapering;

5 (e) Opioid doses can be increased without limit or greater risks;

6 (f) Long-term opioid use improves functioning;

7 (g) Alternative forms of pain relief pose greater risks than opioids;

8 (h) OxyContin provides twelve hours of pain relief; and

9 (i) New formulations of certain opioids successfully deter abuse.

10 229. Each of these propositions was false. The Marketing Defendants knew this, but they
11
12 nonetheless set out to convince physicians, patients, and the public at large of the truth of each of
13 these propositions in order to expand the market for their opioids.
14

15 230. The categories of misrepresentations are offered to organize the numerous statements
16 the Marketing Defendants made and to explain their role in the overall marketing effort, not as a
17 checklist for assessing each Marketing Defendant’s liability. While each of the Marketing
18 Defendants deceptively promoted their opioids specifically, and, together with other Marketing
19 Defendants, opioids generally, not every Marketing Defendant propagated (or needed to propagate)
20 each misrepresentation. Each Marketing Defendant’s conduct, and each misrepresentation,
21 contributed to an overall narrative that aimed to – and did – mislead doctors, patients, and payors
22 about the risks and benefits of opioids. While this complaint endeavors to document examples of
23 each Marketing Defendant’s misrepresentations and the manner in which they were disseminated,
24 they are just that – examples. The complaint is not an exhaustive catalog of the nature and manner
25 of each deceptive statement by each Marketing Defendant.
26
27
28

a. Falsehood No. 1: The Risk of Addiction from Chronic Opioid Therapy Is Low

231. Central to the Marketing Defendants’ promotional scheme was the misrepresentation that opioids are rarely addictive when taken for chronic pain. Through their marketing efforts, the Marketing Defendants advanced the idea that the risk of addiction is low when opioids are taken as prescribed by “legitimate” pain patients. That, in turn, directly led to the expected and intended result that doctors prescribed more opioids to more patients – thereby enriching the Marketing Defendants and substantially contributing to the opioid epidemic.

232. Each Marketing Defendant claimed that the potential for addiction from its opioids was relatively small or non-existent, even though there was no scientific evidence to support those claims. None of them have acknowledged, retracted, or corrected their false statements.

233. In fact, studies have shown that a substantial percentage of long-term users of opioids experience addiction. Addiction can result from the use of any opioid, “even at [the] recommended dose[,]”⁸² and the risk substantially increases with more than three months of use.⁸³ As the CDC Guideline states, “[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder” (a diagnostic term for addiction).⁸⁴

(1) Purdue’s Misrepresentations Regarding Addiction Risk

234. When it launched OxyContin, Purdue knew it would need data to overcome decades of wariness regarding opioid use. It needed some sort of research to back up its messaging. But

⁸² *FDA Announces Safety Labeling Changes and Postmarket Study Requirements for Opioids*, MagMutual.com (Aug. 18, 2016), <https://www.magmutual.com/learning/article/fda-announces-safety-labeling-changes-and-postmarket-study-requirements-opioids>; *see also* Press Release, U.S. Food & Drug Admin., *FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death*, fda.gov (Mar. 22, 2016), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm>.

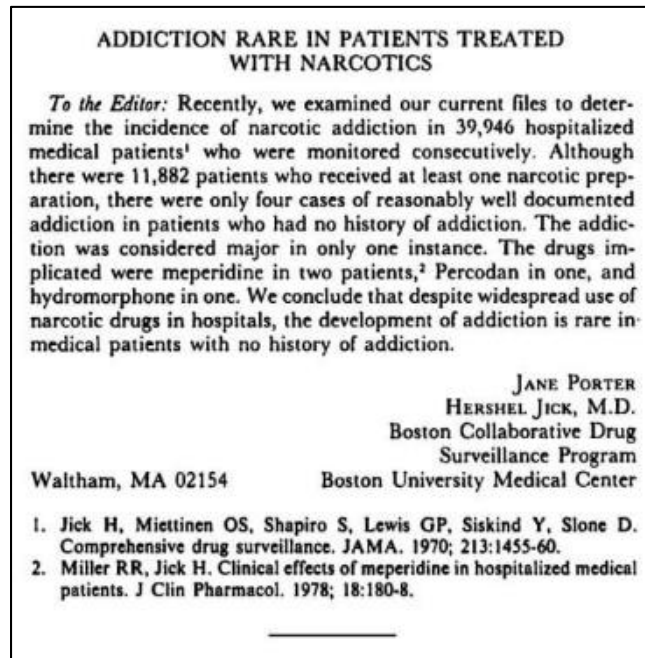
⁸³ Deborah Dowell, M.D., *et al.*, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States 2016*, 65(1) Morbidity & Mortality Wkly. Rep. 1, 21 (Mar. 18, 2016).

⁸⁴ *Id.* at 2.

Purdue had not conducted any studies about abuse potential or addiction risk as part of its application for FDA approval for OxyContin. Purdue (and, later, the other Defendants) found this “research” in the form of a one-paragraph letter to the editor published in the *New England Journal of Medicine* (“*NEJM*”) in 1980.

235. This letter, by Dr. Hershel Jick and Jane Porter (the “Porter & Jick Letter”), declared the incidence of addiction “rare” for patients treated with opioids.⁸⁵ They had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. Porter and Jick considered a patient not addicted if there was no sign of addiction noted in the patient’s records.

236. As Dr. Jick explained to a journalist years later, he submitted the statistics to the *NEJM* as a letter because the data were not robust enough to be published as a study.⁸⁶



⁸⁵ Jane Porter & Hershel Jick, M.D., *Addiction Rare in Patients Treated with Narcotics*, 302(2) *New Eng. J. Med.* 123 (Jan. 10, 1980), <http://www.nejm.org/doi/pdf/10.1056/NEJM198001103020221>.

⁸⁶ Barry Meier, *Pain Killer: A “Wonder” Drug’s Trail of Addiction and Death* 174 (Rodale 2003).

237. Purdue nonetheless began repeatedly citing this letter in promotional and educational materials as evidence of the low risk of addiction, while failing to disclose that its source was a letter to the editor, not a peer-reviewed paper.⁸⁷ Citation of the letter, which was largely ignored for more than a decade, significantly increased after the introduction of OxyContin. While first Purdue and then other Marketing Defendants used it to assert that their opioids were not addictive, “that’s not in any shape or form what we suggested in our letter,” according to Dr. Jick.

238. Purdue specifically used the Porter & Jick Letter in its 1998 promotional video, “I got my life back,” in which Dr. Alan Spanos says: “In fact, the rate of addiction amongst pain patients who are treated by doctors *is much less than 1%*.”⁸⁸ Purdue trained its sales representatives to tell prescribers that fewer than 1% of patients who took OxyContin became addicted. (In 1999, a Purdue-funded study of patients who used OxyContin for headaches found that the addiction rate was 13%.)⁸⁹

239. Other Defendants relied on and disseminated the same distorted messaging. The enormous impact of Defendants’ misleading amplification of this letter was well documented in another letter published in the *NEJM* on June 1, 2017, describing the way the one-paragraph 1980 letter had been irresponsibly cited and in some cases “grossly misrepresented.” In particular, the authors of this letter explained:

[W]e found that a five-sentence letter published in the *Journal* in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American

⁸⁷ Jane Porter & Hershel Jick, M.D., *Addiction Rare in Patients Treated with Narcotics*, 302(2) *New Eng. J. Med.* 123 (Jan. 10, 1980), <http://www.nejm.org/doi/pdf/10.1056/NEJM198001103020221>.

⁸⁸ Our Amazing World, *Purdue Pharma OxyContin Commercial*, YouTube (Sept. 22, 2016), <https://www.youtube.com/watch?v=Er78Dj5hyeI>.

⁸⁹ Patrick R. Keefe, *The Family That Built an Empire of Pain*, *The New Yorker* (Oct. 30, 2017), <https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain>.

1 opioid crisis by helping to shape a narrative that allayed prescribers' concerns about
2 the risk of addiction associated with long-term opioid therapy.⁹⁰

3 240. "It's difficult to overstate the role of this letter," said Dr. David Juurlink of the
4 University of Toronto, who led the analysis. "It was the key bit of literature that helped the opiate
5 manufacturers convince front-line doctors that addiction is not a concern."⁹¹

6 241. Alongside its use of the Porter & Jick Letter, Purdue also crafted its own materials
7 and spread its deceptive message through numerous additional channels. In its 1996 press release
8 announcing the release of OxyContin, for example, Purdue declared: "The fear of addiction is
9 exaggerated."⁹²

10 242. At a hearing before the House of Representatives' Subcommittee on Oversight and
11 Investigations of the Committee on Energy and Commerce in August 2001, Purdue emphasized
12 "legitimate" treatment, dismissing cases of overdose and death as something that would not befall
13 "legitimate" patients: "Virtually all of these reports involve people who are abusing the medication,
14 not patients with legitimate medical needs under the treatment of a healthcare professional."⁹³

15 243. Purdue spun this baseless "legitimate use" distinction out even further in a patient
16 brochure about OxyContin called "A Guide to Your New Pain Medicine and how to become A
17 Partner Against Pain." In response to the question "[a]ren't opioid pain medications like OxyContin
18 Partner Against Pain." In response to the question "[a]ren't opioid pain medications like OxyContin
19 Partner Against Pain."

20 ⁹⁰ Pamela T.M. Leung, B.Sc. Pharm., *et al.*, *A 1980 Letter on the Risk of Opioid Addiction*, 376
21 New Eng. J. Med. 2194, 2194-95 (June 1, 2017), <http://www.nejm.org/doi/full/10.1056/NEJMc1700150>.

22 ⁹¹ Marilyn Marchione, Assoc. Press, *Painful words: How a 1980 letter fueled the opioid epidemic*,
23 STAT News (May 31, 2017), <https://www.statnews.com/2017/05/31/opioid-epidemic-nejm-letter/>.

24 ⁹² Press Release, Purdue Pharma, L.P., *New Hope for Millions of Americans Suffering from*
25 *Persistent Pain: Long-Acting OxyContin Tablets Now Available to Relieve Pain* (May 31, 1996),
<http://documents.latimes.com/oxycontin-press-release-1996/>.

26 ⁹³ *OxyContin: Its Use and Abuse: Hearing Before the H. Subcomm. on Oversight and*
27 *Investigations of the Committee on Energy and Commerce*, 107th Cong. 1 (Aug. 28, 2001)
28 (Statement of Michael Friedman, Executive Vice President, Chief Operating Officer, Purdue
Pharma, L.P.), <https://www.gpo.gov/fdsys/pkg/CHRG-107hhrg75754/html/CHRG-107hhrg75754.htm>.

1 Tablets ‘addicting,’” Purdue claimed that there was no need to worry about addiction if taking
2 opioids for legitimate “medical” purposes:

3 Drug addiction means using a drug to get “high” rather than to relieve pain.
4 You are taking opioid pain medication for medical purposes. The medical purposes
5 are clear and the effects are beneficial, not harmful.

6 244. Sales representatives marketed OxyContin as a product ““to start with and to stay
7 with.””⁹⁴ Sales representatives also received training in overcoming doctors’ concerns about
8 addiction with talking points they knew to be untrue about the drug’s abuse potential. One of
9 Purdue’s early training memos compared doctor visits to “firing at a target,” declaring that “[a]s you
10 prepare to fire your ‘message,’ you need to know where to aim and what you want to hit!”⁹⁵
11 According to the memo, the target is physician resistance based on concern about addiction: “The
12 physician wants pain relief for these patients without addicting them to an opioid.”⁹⁶

13 245. Purdue, through its unbranded website *Partners Against Pain*, stated the following:
14 “Current Myth: Opioid addiction (psychological dependence) is an important clinical problem in
15 patients with moderate to severe pain treated with opioids. Fact: Fears about psychological
16 dependence are exaggerated when treating appropriate pain patients with opioids.” “Addiction risk
17 also appears to be low when opioids are dosed properly for chronic, noncancer pain.”⁹⁷
18

19
20 ⁹⁴ Patrick R. Keefe, *The Family That Built an Empire of Pain*, The New Yorker
21 (Oct. 30, 2017), <https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain>.

22 ⁹⁵ Barry Meier, *Pain Killer: A “Wonder” Drug’s Trail of Addiction and Death* 201, 202, 204
23 (Rodale 2003).

24 ⁹⁶ *Id.*

25 ⁹⁷ *Partners Against Pain* consists of both a website, styled as an “advocacy community” for better
26 pain care, and a set of medical education resources distributed to prescribers by sales representatives.
27 It has existed since at least the early 2000s and has been a vehicle for Purdue to downplay the risks
28 of addiction from long-term opioid use. One early pamphlet, for example, answered concerns about
29 OxyContin’s addictiveness by claiming: “Drug addiction means using a drug to get ‘high’ rather
30 than to relieve pain. You are taking opioid pain medication for medical purposes. The medical
31 purposes are clear and the effects are beneficial, not harmful.”

246. Former sales representative Steven May, who worked for Purdue from 1999 to 2005, explained to a journalist how he and his coworkers were trained to overcome doctors' objections to prescribing opioids. The most common objection he heard about prescribing OxyContin was that "it's just too addictive."⁹⁸ May and his coworkers were trained to "refocus" doctors on "legitimate" pain patients, and to represent that "legitimate" patients would not become addicted. In addition, they were trained to say that the 12-hour dosing made the extended-release opioids less "habit-forming" than painkillers that need to be taken every four hours.

247. According to interviews with prescribers and former Purdue sales representatives, Purdue has continued to distort or omit the risk of addiction while failing to correct its earlier misrepresentations, leaving many doctors with the false impression that pain patients will only rarely become addicted to opioids.

248. With regard to addiction, Purdue's label for OxyContin has not sufficiently disclosed the true risks to, and experiences of, its patients. Until 2014, the OxyContin label stated in a black-box warning that opioids have "abuse potential" and that the "risk of abuse is increased in patients with a personal or family history of substance abuse."

249. However, the FDA made clear to Purdue as early as 2001 that the disclosures in its OxyContin label were insufficient. Senior FDA officials met with Purdue on April 23, 2001 to "provide comments and suggestions on a Risk Management program for OxyContin." Among other issues, the FDA noted that Purdue should add a black-box warning for overdose, abuse, and death to OxyContin's label. Purdue acknowledged that it was aware of abuse of OxyContin orally (without tampering), as well as by snorting or injecting. It was not, the FDA explained, a matter of changing a few words in OxyContin's label; Dr. Cynthia McCormick, then director of the FDA division

⁹⁸ Interview by Patrick Keefe with Steven Mays, former sales representative for Purdue Pharma, L.P., *How OxyContin Was Sold to the Masses*, The New Yorker (Oct. 27, 2017), <https://www.newyorker.com/podcast/the-new-yorker-radio-hour/how-oxycontin-was-sold-to-the-masses>.

1 overseeing pain medication, declared that “‘major overhaul is my message.’ The prescribing of
2 OxyContin is creeping into a whole population of people where it doesn’t belong. Just rewriting the
3 abuse and dependence section won’t help much, that part of the insert is not a pivot point.”

4 250. Another FDA participant asked that Purdue “refocus [its] promotional materials and
5 make the risks of abuse and diversion more prominent.” In short, the FDA advised Purdue “that the
6 information put in the label back at the time of product approval did not adequately address the risks
7 associated with this product and this needs to be corrected.”

8 251. In 2001, Purdue revised the indication and warnings for OxyContin, but did not go
9 nearly as far as the FDA recommended or the known risks of the product demanded. In the United
10 States, Purdue ceased distributing the 160 mg tablet of OxyContin. While Purdue agreed to
11 “consider” changes to its label, it also expressed a reluctance to make significant changes not
12 required for other prescription opioids. Dr. McCormick noted that the issues discussed at the
13 meeting were specific to OxyContin and that, while the FDA would talk with Purdue’s competitors,
14 “‘we have a problem here and now with OxyContin.’ In due time other manufacturers will be
15 contacted but the first problem is this product.”

16 252. In the end, Purdue narrowed the recommended use of OxyContin to situations when
17 “a continuous, around-the-clock analgesic is needed for an extended period of time” and added a
18 warning that “[t]aking broken, chewed, or crushed OxyContin tablets” could lead to a “potentially
19 fatal dose.” However, Purdue did not, until 2014, change the label, as the FDA suggested, to
20 indicate that OxyContin should not be the first therapy, or even the first opioid, used, and did not
21 disclose the incidence or risk of overdose and death even when OxyContin was not abused. Purdue
22 announced the label changes in a letter to health care providers but did not, as the FDA suggested,
23 issue “a Medguide for patients on the risks of overdose and the abuse of opioids as well as risks for
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(2) Endo's Misrepresentations Regarding Addiction Risk

255. Until April 2012, Endo’s website for Opana, *www.Opana.com*, stated that “[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted.”

257. One of the Front Groups with which Endo worked most closely was the American Pain Foundation (“APF”), described more fully below. Endo provided substantial assistance to, and exercised editorial control over, the deceptive and misleading messages that APF conveyed through

1 its National Initiative on Pain Control (“NIPC”) and its website *www.PainKnowledge.com*, which
 2 claimed that “[p]eople who take opioids as prescribed usually do not become addicted.”⁹⁹

3 258. Another Endo website, *www.PainAction.com*, stated: “Did you know? Most chronic
 4 pain patients do not become addicted to the opioid medications that are prescribed for them.”

5 259. In a brochure available on *www.PainKnowledge.com*, titled *Pain: Opioid Facts*,
 6 Endo-sponsored NIPC stated that “people who have no history of drug abuse, including tobacco, and
 7 use their opioid medication as directed will probably not become addicted.” In numerous patient
 8 education pamphlets, Endo repeated this deceptive message.
 9

10 260. In a patient education pamphlet titled *Understanding Your Pain: Taking Oral Opioid*
 11 *Analgesics*, Endo answers the hypothetical patient question “What should I know about opioids and
 12 addiction?” by focusing on explaining what addiction is (“a chronic brain disease”) and is not
 13 (“[t]aking opioids for pain relief”). It goes on to explain that “[a]ddicts take opioids for other
 14 reasons, such as unbearable emotional problems. Taking opioids as prescribed for pain relief is not
 15 addiction.” This publication is still available online.
 16

17 261. An Endo publication, *Living with Someone with Chronic Pain*, stated, “Most health
 18 care providers who treat people with pain agree that most people do not develop an addiction
 19 problem.” A similar statement appeared on the Endo website, *www.Opana.com*, until at least April
 20 2012.
 21
 22
 23
 24

25 ⁹⁹ Endo was one of the APF’s biggest financial supporters, providing more than half of the \$10
 26 million APF received from opioid manufacturers during its lifespan. Endo was the sole funder of
 27 NIPC and selected APF to manage NIPC. Internal Endo documents indicate that Endo was
 28 responsible for NIPC curriculum development, web posting, and workshops, developed and
 reviewed NIPC content, and took a substantial role in distributing NIPC and APF materials. Endo
 projected that it would be able to reach tens of thousands of prescribers nationwide through the
 distribution of NIPC materials.

262. In addition, a 2009 patient education publication, *Pain: Opioid Therapy*, funded by Endo and posted on *www.PainKnowledge.com*, omitted addiction from the “common risks” of opioids, as shown below:

As with any medication, there are some side effects that are associated with opioid therapy. The most common side effects that occur with opioid use include the following:

- ▶ Constipation
- ▶ Drowsiness
- ▶ Confusion
- ▶ Nausea
- ▶ Itching
- ▶ Dizziness
- ▶ Shortness of breath

Your healthcare provider can help to address and, in some cases, prevent side effects that may occur as a result of opioid treatment. Less severe side effects, including nausea, itching, or drowsiness, typically go away within a few days without the need for further treatment. If you experience any side effects, you should let your healthcare provider know immediately.

(3) Janssen’s Misrepresentations Regarding Addiction Risk

263. Janssen likewise misrepresented the addiction risk of opioids on its websites and print materials. One website, *Let’s Talk Pain*, states, among other things, that “the stigma of drug addiction and abuse” associated with the use of opioids stemmed from a “lack of understanding about addiction.” (Although Janssen described the website internally as an unbranded third-party program, it carried Janssen’s trademark and copy approved by Janssen.)

264. The *Let’s Talk Pain* website also perpetuated the concept of pseudoaddiction, associating patient behaviors such as “drug seeking,” “clock watching,” and “even illicit drug use or deception” with undertreated pain, which can be resolved with “effective pain management.” In August 2009, a “12 month review” of the *Let’s Talk Pain* website manuscript confirmed that the website’s contents included statements regarding pseudoaddiction and illustrated Janssen’s control over the website and awareness of its contents.

1 265. A Janssen unbranded website, www.PrescribeResponsibly.com, states that concerns
2 about opioid addiction are “overestimated” and that “true addiction occurs only in a small percentage
3 of patients.”¹⁰⁰

4 266. Janssen reviewed, edited, approved, and distributed a patient education guide entitled
5 *Finding Relief: Pain Management for Older Adults*, which, as seen below, described as “myth” the
6 claim that opioids are addictive, and asserted as fact that “[m]any studies show that opioids are rarely
7 addictive when used properly for the management of chronic pain.” Until recently, this guide was
8 still available online.
9

Opioid myths

Myth: Opioid medications are
always addictive.

Fact: Many studies show that
opioids are *rarely* addictive when
used properly for the management of
chronic pain.

18 267. Janssen’s website for Duragesic included a section addressing “Your Right to Pain
19 Relief” and a hypothetical patient’s fear that “I’m afraid I’ll become a drug addict.” The website’s
20 response: “Addiction is relatively rare when patients take opioids appropriately.”
21

22 268. According to an internal marketing assessment, Janssen sales representatives were
23 trained to emphasize that Nucynta ER had fewer side effects than other opioids, though, upon
24 information and belief, this was an untrue and unsubstantiated superiority claim.
25

26
27 ¹⁰⁰ Keith Candiotti, M.D., *Use of Opioid Analgesics in Pain Mgmt.*, Prescribe Responsibly,
28 <https://web.archive.org/web/20151119055136/http://www.prescriberesponsibly.com/articles/opioid-pain-management> (last visited Mar. 13, 2020).

269. Janssen also conducted a research study on prescribers regarding the visual aids for the marketing of Nucynta ER. Doctors reportedly were interested that Nucynta was described as appropriate for patients at risk for addiction and as a way to avoid addictive narcotics for young people. Additionally, doctors identified the advantages of Nucynta, which included that it was potentially less addicting than other opioids and had a lower street value.

270. Janssen also published a patient guide, *Patient Booklet Answers to Your Questions – Duragesic*, which stated that “[a]ddiction is relatively rare when patients take opioids appropriately.”

271. Janssen recognized that this misrepresentation was particularly important to payors, who had a “negative” reaction to covering an addictive drug for a chronic condition for which non-narcotic drugs were available.

(4) Cephalon’s Misrepresentations Regarding Addiction Risk

272. Cephalon sponsored and facilitated the development of a guidebook, *Opioid Medications and REMS: A Patient’s Guide*, which included claims that “patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids.” Similarly, Cephalon sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.

273. For example, a 2003 Cephalon-sponsored CME presentation, titled *Pharmacologic Management of Breakthrough or Incident Pain*, posted by Medscape, LLC in February 2003, teaches:

[C]hronic pain is often undertreated, particularly in the noncancer patient population. . . . The continued stigmatization of opioids and their prescription, coupled with often unfounded and self-imposed physician fear of dealing with the highly regulated distribution system for opioid analgesics, remains a barrier to effective pain management and must be addressed. Clinicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest in substance abuse. In fact, patient fears of developing substance abuse behaviors such as addiction often lead to undertreatment

1 of pain. The concern about patients with chronic pain becoming addicted to opioids
 2 during long-term opioid therapy may stem from confusion between physical
 3 dependence (tolerance) and psychological dependence (addiction) that manifests as
 4 drug abuse.¹⁰¹

5 274. An internal “educational” document claimed that “in patients without personal or
 6 family history of substance abuse, addiction resulting from exposure to opioid therapy is
 7 uncommon.” The document continued, “Like patients, caregivers may need reassurance that few
 8 people using opioids for a legitimate medical reason become addicted to the drug, and that physical
 9 dependence to a drug is easily overcome through scheduled dosing decreases” Upon
 10 information and belief, this Cephalon “learning module” was used to train sales representatives for
 11 their interactions with prescribers.

12 (5) Actavis’s Misrepresentations Regarding 13 Addiction Risk

14 275. Through its “Learn More about customized pain control with Kadian” material,
 15 Actavis claimed that it is possible to become addicted to morphine-based drugs like Kadian, but that
 16 it is “less likely” to happen in those who “have never had an addiction problem.” The piece goes on
 17 to advise that a need for a “dose adjustment” is the result of tolerance, and “not addiction.”

18 276. Training for Actavis sales representatives deceptively minimizes the risk of addiction
 19 by: (i) attributing addiction to “predisposing factors” like family history of addiction or psychiatric
 20 disorders; (ii) repeatedly emphasizing the difference between substance dependence and substance
 21 abuse; and (iii) using the term pseudoaddiction, which, as described below, dismisses evidence of
 22 addiction as the undertreatment of pain and, dangerously, counsels doctors to respond to its signs
 23 with more opioids.

24 277. Actavis conducted a market study on takeaways from prescribers’ interactions with
 25 Kadian sales representatives. The doctors had a strong recollection of the sales representatives’
 26

27 ¹⁰¹ Michael J. Brennan, *et al.*, *Pharmacologic Management of Breakthrough or Incident Pain*,
 28 Medscape, <http://www.medscape.org/viewarticle/449803> (behind paywall).

(6) Mallinckrodt's Misrepresentations Regarding Addiction Risk

279. As described below, Mallinckrodt promoted its branded opioids Exalgo and Xartemis XR, and opioids generally, in a campaign that consistently mischaracterized the risk of addiction. Mallinckrodt did so through its website and sales force, as well as through unbranded communications distributed through the “C.A.R.E.S. Alliance” it created and led.

280. Mallinckrodt in 2010 created the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it describes as “a coalition of national patient safety, provider and drug diversion organizations that are focused on reducing opioid pain medication abuse and increasing responsible prescribing habits.” The “C.A.R.E.S. Alliance” itself is a service mark of Mallinckrodt LLC (and was previously a service mark of Mallinckrodt, Inc.) copyrighted and registered as a trademark by Covidien, its former parent company. Materials distributed by the C.A.R.E.S. Alliance, however, include unbranded publications that do not disclose a link to Mallinckrodt.

281. By 2012, Mallinckrodt, through the C.A.R.E.S. Alliance, was promoting a book titled *Defeat Chronic Pain Now!* This book is still available online. The false claims and misrepresentations in this book include the following statements:

- “Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction.”
- “It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy.”
- “When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving.”
- “Only a minority of chronic pain patients who are taking long-term opioids develop tolerance.”
- “**The bottom line:** Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction.”
- “Here are the facts. It is very uncommon for a person with chronic pain to become ‘addicted’ to narcotics IF (1) he doesn’t have a prior history of any addiction and (2) he only takes the medication to treat pain.”
- “Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction.”

1 282. In a 2013 *Mallinckrodt Pharmaceuticals Policy Statement Regarding the Treatment*
 2 *of Pain and Control of Opioid Abuse*, which is still available online, Mallinckrodt stated that,
 3 “[s]adly, even today, pain frequently remains undiagnosed and either untreated or undertreated,”
 4 citing to a report that concludes “the majority of people with pain use their prescription drugs
 5 properly, are not a source of misuse, and should not be stigmatized or denied access because of the
 6 misdeeds or carelessness of others.”

7
 8 283. The Marketing Defendants’ suggestions that the opioid epidemic is the result of bad
 9 patients who manipulate doctors to obtain opioids illicitly helped further their marketing scheme, but
 10 is at odds with the facts. While there are certainly patients who unlawfully obtain opioids, they are a
 11 small minority. For example, patients who “doctor-shop” – *i.e.*, visit multiple prescribers to obtain
 12 opioid prescriptions – are responsible for roughly 2% of opioid prescriptions. The epidemic of
 13 opioid addiction and abuse is overwhelmingly a problem of false marketing (and unconstrained
 14 distribution) of the drugs, not problem patients.

15
 16 **b. Falsehood No. 2: To the Extent There Is a Risk of**
 17 **Addiction, It Can Be Easily Identified and Managed**

18 284. While continuing to maintain that most patients can safely take opioids long term for
 19 chronic pain without becoming addicted, the Marketing Defendants assert that to the extent that
 20 **some** patients are at risk of opioid addiction, doctors can effectively identify and manage that risk by
 21 using screening tools or questionnaires. In materials they produced, sponsored, or controlled,
 22 Defendants instructed patients and prescribers that screening tools can identify patients predisposed
 23 to addiction, thus making doctors feel more comfortable prescribing opioids to their patients and
 24 patients more comfortable starting opioid therapy for chronic pain. These tools, they say, identify
 25 those with higher addiction risks (stemming from personal or family histories of substance use,
 26 mental illness, trauma, or abuse) so that doctors can then more closely monitor those patients.
 27
 28

1 285. Purdue shared its *Partners Against Pain* “Pain Management Kit,” which contains
 2 several screening tools and catalogues of Purdue materials, including these tools, with prescribers.
 3 Janssen, on its website www.PrescribeResponsibly.com, states that the risk of opioid addiction “can
 4 usually be managed” through tools such as opioid agreements between patients and doctors.¹⁰² The
 5 website, which directly provides screening tools to prescribers for risk assessments, includes a
 6 “[f]our question screener” to purportedly help physicians identify and address possible opioid
 7 misuse.¹⁰³

9 286. Purdue and Cephalon sponsored the APF’s *Treatment Options: A Guide for People*
 10 *Living with Pain* (2007), which also falsely reassured patients that opioid agreements between
 11 doctors and patients can “ensure that you take the opioid as prescribed.”

12 287. Purdue sponsored a 2011 webinar taught by Dr. Lynn Webster, entitled *Managing*
 13 *Patient’s Opioid Use: Balancing the Need and Risk*, which misleadingly taught prescribers that
 14 screening tools, urine tests, and patient agreements have the effect of preventing “overuse of
 15 prescriptions” and “overdose deaths.”

17 288. Purdue sponsored a 2011 CME program titled *Managing Patient’s Opioid Use:*
 18 *Balancing the Need and Risk*. This presentation deceptively instructed prescribers that screening
 19 tools, patient agreements, and urine tests prevented “overuse of prescriptions” and “overdose
 20 deaths.”

22 289. Purdue also funded a 2012 CME program called *Chronic Pain Management and*
 23 *Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*. The presentation deceptively

25 ¹⁰² Howard A. Heit, M.D., FACP, FASAM & Douglas L. Gourlay, M.D., M.Sc., FRCPC, FASAM,
 26 *What a Prescriber Should Know Before Writing the First Prescription*, Prescribe Responsibly,
<http://www.prescriberesponsibly.com/articles/before-prescribing-opioids#pseudoaddiction> (last
 modified July 2, 2015).

27 ¹⁰³ *Risk Assessment Resources*, Prescribe Responsibly, [http://www.prescriberesponsibly.com/risk-](http://www.prescriberesponsibly.com/risk-assessment-resources)
 28 [assessment-resources](http://www.prescriberesponsibly.com/risk-assessment-resources) (last modified July 2, 2015).

1 instructed doctors that, through the use of screening tools, more frequent refills, and other
2 techniques, even high-risk patients showing signs of addiction could be treated with opioids.

3 290. Endo paid for a 2007 supplement available for continuing education credit in the
4 *Journal of Family Practice* written by a doctor who became a member of Endo's speakers' bureau in
5 2010. This publication, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, (i)
6 recommended screening patients using tools like the Opioid Risk Tool ("ORT"), created by Dr.
7 Webster and linked to Janssen, or Screener and Opioid Assessment for Patients with Pain, and (ii)
8 taught that patients at high risk of addiction could safely receive chronic opioid therapy using a
9 "maximally structured approach" involving toxicology screens and pill counts. The ORT was linked
10 to Endo-supported websites, as well.

12 291. There are three fundamental flaws in the Marketing Defendants' representations that
13 doctors can consistently identify and manage the risk of addiction. First, there is no reliable
14 scientific evidence that doctors can depend on the screening tools currently available to materially
15 limit the risk of addiction. Second, there is no reliable scientific evidence that high-risk patients
16 identified through screening can take opioids long term without triggering addiction, even with
17 enhanced monitoring. Third, there is no reliable scientific evidence that patients who are not
18 identified through such screening can take opioids long term without significant danger of addiction.

20 **c. Falsehood No. 3: Signs of Addictive Behavior Are**
21 **"Pseudoaddiction," Requiring More Opioids**

22 292. The Marketing Defendants instructed patients and prescribers that signs of addiction
23 are actually indications of untreated pain, such that the appropriate response is to prescribe even
24 more opioids. Dr. J. David Haddox, who later became a Senior Medical Director for Purdue,
25 published a study in 1989 coining the term "pseudoaddiction," which he characterized as "the
26 iatrogenic syndrome of abnormal behavior developing as a direct consequence of inadequate pain
27 management."

1 management.”¹⁰⁴ In other words, people on prescription opioids who exhibited classic signs of
 2 addiction – for example, asking for more and higher doses of opioids, self-escalating their doses, or
 3 claiming to have lost prescriptions in order to get more opioids – were not addicted, but rather
 4 simply suffering from undertreatment of their pain.

5 293. In the materials and outreach they produced, sponsored, or controlled, Defendants
 6 made each of these misrepresentations and omissions, and have never acknowledged, retracted, or
 7 corrected them.
 8

9 294. Cephalon, Endo, and Purdue sponsored the Federation of State Medical Boards’
 10 (“FSMB”) *Responsible Opioid Prescribing* (2007) written by Dr. Scott Fishman and discussed in
 11 more detail below, which taught that behaviors such as “requesting drugs by name,” “demanding or
 12 manipulative behavior,” seeing more than one doctor to obtain opioids, and hoarding, which are
 13 signs of genuine addiction, are all really signs of “pseudoaddiction.”
 14

15 295. Purdue posted an unbranded pamphlet entitled *Clinical Issues in Opioid Prescribing*
 16 on its unbranded website, www.PartnersAgainstPain.com, in 2005, and circulated this pamphlet
 17 through at least 2007 and on its website through at least 2013. The pamphlet listed conduct,
 18 including “illicit drug use and deception,” that it claimed was not evidence of true addiction but
 19 “pseudoaddiction” caused by untreated pain.
 20

21 296. According to documents provided by a former Purdue detailer, sales representatives
 22 were trained and tested on the meaning of pseudoaddiction, from which it can be inferred that sales
 23 representatives were directed to, and did, describe pseudoaddiction to prescribers. Purdue’s “Pain
 24 Management Kit” is another example of a publication used by Purdue’s sales force that endorses
 25 pseudoaddiction by claiming that “pain-relief seeking behavior can be mistaken for drug-seeking
 26

27 ¹⁰⁴ David E. Weissman & J. David Haddox, *Opioid Pseudoaddiction – An Iatrogenic Syndrome*,
 28 36(3) *Pain* 363, 363-66 (Mar. 1989), <https://www.ncbi.nlm.nih.gov/pubmed/2710565> (“Iatrogenic” describes a condition induced by medical treatment).

1 behavior.” Upon information and belief, the kit was in use from roughly 2011 through at least June
2 2016.

3 297. Similarly, internal documents show that Endo trained its sales representatives to
4 promote the concept of pseudoaddiction. A training module taught sales representatives that
5 addiction and pseudoaddiction were commonly confused. The module went on to state that: “The
6 physician can differentiate addiction from pseudoaddiction by speaking to the patient about his/her
7 pain and increasing the patient’s opioid dose to increase pain relief.”

9 298. Endo also sponsored an NIPC CME program in 2009, titled *Chronic Opioid Therapy:
10 Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction and listed
11 “[d]ifferentiation among states of physical dependence, tolerance, pseudoaddiction, and addiction”
12 as an element to be considered in awarding grants to CME providers.

14 299. Upon information and belief, Endo itself has repudiated the concept of
15 pseudoaddiction. In finding that “[t]he pseudoaddiction concept has never been empirically
16 validated and in fact has been abandoned by some of its proponents,” the New York Attorney
17 General (“NY AG”), in a 2016 settlement with Endo, reported that “Endo’s Vice President for
18 Pharmacovigilance and Risk Management testified to [the NY AG] that he was not aware of any
19 research validating the ‘pseudoaddiction’ concept” and acknowledged the difficulty in distinguishing
20 “between addiction and ‘pseudoaddiction.’”¹⁰⁵ Endo thereafter agreed not to “use the term
21 ‘pseudoaddiction’ in any training or marketing” in New York.

23 300. Janssen sponsored, funded, and edited a website called *Let’s Talk Pain*, which in
24 2009 stated “pseudoaddiction . . . refers to patient behaviors that may occur when ***pain is***
25 ***undertreated*** Pseudoaddiction is different from true addiction because such behaviors can be

27 ¹⁰⁵ Attorney General of the State of New York, *In the Matter of Endo Health Solutions Inc. & Endo*
28 *Pharmaceuticals Inc.*, Assurance No.: 15-228, Assurance of Discontinuance Under Executive Law
Section 63. Subdivision 15 at 7.

resolved with effective pain management.” This website was accessible online until at least May 2012.

301. Janssen also currently runs a website, *www.PrescribeResponsibly.com*, which claims that concerns about opioid addiction are “overestimated” and describes pseudoaddiction as “a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically when the pain is treated appropriately the inappropriate behavior ceases.”¹⁰⁶

302. The CDC Guideline nowhere recommends attempting to provide more opioids to patients exhibiting symptoms of addiction. Dr. Lynn Webster, a “key opinion leader” discussed below, admitted that pseudoaddiction “is already something we are debunking as a concept” and became “too much of an excuse to give patients more medication. It led us down a path that caused harm.”

d. Falsehood No. 4: Opioid Withdrawal Can Be Avoided by Tapering

303. In an effort to underplay the risk and impact of addiction, the Marketing Defendants falsely claimed that, while patients become physically dependent on opioids, physical dependence is not the same as addiction and can be easily addressed, if and when pain relief is no longer desired, by gradually tapering patients’ doses to avoid the adverse effects of withdrawal. Defendants failed to disclose the extremely difficult and painful effects that patients can experience when they are removed from opioids – adverse effects that also make it less likely that patients will be able to stop using the drugs. Defendants also failed to disclose how difficult it is for patients to stop using opioids after they have used them for prolonged periods.

¹⁰⁶ Howard A. Heit, M.D., FACP, FASAM & Douglas L. Gourlay, M.D., M.Sc., FRCPC, FASAM, *What a Prescriber Should Know Before Writing the First Prescription*, Prescribe Responsibly, <http://www.prescriberesponsibly.com/articles/before-prescribing-opioids#pseudoaddiction> (last modified July 2, 2015).

1 304. A non-credit educational program sponsored by Endo, *Persistent Pain in the Older*
 2 *Adult*, claimed that withdrawal symptoms, which make it difficult for patients to stop using opioids,
 3 could be avoided by simply tapering a patient's opioid dose over ten days. However, this claim is at
 4 odds with the experience of patients addicted to opioids. Most patients who have been taking
 5 opioids regularly will, upon stopping treatment, experience withdrawal characterized by intense
 6 physical and psychological effects, including anxiety, nausea, headaches, and delirium, among
 7 others. This painful and arduous struggle to terminate use can leave many patients unwilling or
 8 unable to give up opioids and heightens the risk of addiction.

10 305. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its*
 11 *Management*, which taught that "[s]ymptoms of physical dependence can often be ameliorated by
 12 gradually decreasing the dose of medication during discontinuation," but did not disclose the
 13 significant hardships that often accompany cessation of use.

15 306. To this day, the Marketing Defendants have not corrected or retracted their
 16 misrepresentations regarding tapering as a solution to opioid withdrawal.

17 **e. Falsehood No. 5: Opioid Doses Can Be Increased**
 18 **Without Limit or Greater Risks**

19 307. In materials they produced, sponsored or controlled, the Marketing Defendants
 20 instructed prescribers that they could safely increase a patient's dose to achieve pain relief. Each of
 21 the Marketing Defendants' claims was deceptive in that it omitted warnings of increased adverse
 22 effects that occur at higher doses, effects confirmed by scientific evidence.

23 308. These misrepresentations were integral to the Marketing Defendants' promotion of
 24 prescription opioids. As discussed above, patients develop a tolerance to opioids' analgesic effects,
 25 so that achieving long-term pain relief requires constantly increasing the dose.

26 309. In a 1996 sales memo regarding OxyContin, for example, a regional manager for
 27 Purdue instructed sales representatives to inform physicians that there is "no[] upward limit" for
 28

dosing and ask

And the 2003 C

dose up to 320

A Guide to Titration of OxyContin®



tin.”¹⁰⁷

asing a

310. In addition, sales representatives aggressively pushed doctors to prescribe stronger doses of opioids. For example, one Purdue sales representative wrote about how his regional manager would drill the sales team on their upselling tactics:

It went something like this. “Doctor, what is the highest dose of OxyContin you have ever prescribed?” “20mg Q12h.” “Doctor, if the patient tells you their pain score is still high you can increase the dose 100% to 40mg Q12h, will you do that?” “Okay.” “Doctor, what if that patient then came back and said their pain score was still high, did you know that you could increase the OxyContin dose to 80mg Q12h, would you do that?” “I don’t know, maybe.” “Doctor, but you do agree that you would at least Rx the 40mg dose, right?” “Yes.”

The next week the rep would see that same doctor and go through the same discussion with the goal of selling higher and higher doses of OxyContin.

311. These misrepresentations were particularly dangerous. As noted above, opioid doses at or above 50 MME/day double the risk of overdose compared to 20 MME/day, and 50 MME is

¹⁰⁷ Letter from Windell Fisher, Purdue Regional Manager, to B. Gergely, Purdue Employee (Nov. 7, 1996), <http://documents.latimes.com/sales-manager-on-12-hour-dosing-1996/> (last updated May 5, 2016).

1 equal to just 33 mg of oxycodone. The recommendation of 320 mg every twelve hours is ten times
2 that.

3 312. In its 2010 Risk Evaluation and Mitigation Strategy (“REMS”) for OxyContin,
4 however, Purdue does not address the increased risk of respiratory depression and death from
5 increasing the dose, and instead advises prescribers that “dose adjustments may be made every 1-2
6 days”; “it is most appropriate to increase the q12h dose”; the “total daily dose can usually be
7 increased by 25% to 50%”; and if “significant adverse reactions occur, treat them aggressively until
8 they are under control, then resume upward titration.”¹⁰⁸

10 313. Endo sponsored a website, *www.PainKnowledge.com*, which claimed that opioids
11 may be increased until “you are on the right dose of medication for your pain,” at which point further
12 dose increases would not be required.

13 314. Endo also published on its website a patient education pamphlet entitled
14 *Understanding Your Pain: Taking Oral Opioid Analgesics*. In Q&A format, it asked, “If I take the
15 opioid now, will it work later when I really need it?” The response is, “The dose can be increased
16 You won’t ‘run out’ of pain relief.”

18 315. Purdue and Cephalon sponsored APF’s *Treatment Options: A Guide for People*
19 *Living with Pain* (2007), which taught patients that opioids have “no ceiling dose” and therefore are
20 safer than NSAIDs.

22 316. According to internal documents, Janssen sales representatives were trained to
23 explain to physicians that patients’ pain was reduced at higher doses and that they were undertreating
24 pain by prescribing lower doses. For example, a 2012 *Nucynta ER Messaging Evolution Full Report*
25 instructs sales representatives to overcome primary care provider’s objections to high doses.

27 ¹⁰⁸ Purdue Pharma, L.P., *OxyContin Risk Evaluation and Mitigation Strategy* 31 (last modified Nov.
28 2010), <https://web.archive.org/web/20170215190303/https://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM220990.pdf>.

1 317. Higher dose prescribing was particularly important to Janssen because it knew that
 2 doctors did not believe that Nucynta ER provided adequate or equivalent pain relief. A few of the
 3 doctors who participated in the study voiced concerns over prescribing higher doses. In response,
 4 sales representatives were trained to address concerns by emphasizing approved dosing ranges.

5 318. The Marketing Defendants were aware of the greater dangers high-dose opioids
 6 posed. In 2013, the FDA acknowledged “that the available data do suggest a relationship between
 7 increasing opioid dose and risk of certain adverse events” and that studies “appear to credibly
 8 suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose
 9 mortality.” A study of the Veterans Health Administration from 2004 to 2008 found the rate of
 10 overdose deaths is directly related to maximum daily dose.
 11

12 **f. Falsehood No. 6: Long-Term Opioid Use Improves**
 13 **Functioning**

14 319. Despite the lack of evidence of improved function and the existence of evidence to
 15 the contrary, the Marketing Defendants consistently promoted opioids as capable of improving
 16 patients’ function and quality of life because they viewed these claims as a critical part of their
 17 marketing strategies. In recalibrating the risk-benefit analysis for opioids, increasing the perceived
 18 benefits of treatment was necessary to overcome its risks.
 19

20 320. Janssen, for example, promoted Duragesic as improving patients’ functioning and
 21 work productivity through an ad campaign that included the following statements: “[w]ork,
 22 uninterrupted,” “[l]ife, uninterrupted,” “[g]ame, uninterrupted,” “[c]hronic pain relief that supports
 23 functionality” and “[i]mprove[s] . . . physical and social functioning.”

24 321. Purdue noted the need to compete with this messaging, despite the lack of data
 25 supporting improvement in quality of life with OxyContin treatment:
 26

27 Janssen has been stressing decreased side effects, especially constipation, as well as
 28 patient quality of life, as supported by patient rating compared to sustained release
 morphine We do not have such data to support OxyContin promotion. . . . In
 addition, Janssen has been using the “life uninterrupted” message in promotion of

1 Duragesic for non-cancer pain, stressing that Duragesic “helps patients think less
2 about their pain.” This is a competitive advantage based on our inability to make any
quality of life claims.¹⁰⁹

3 322. Despite its acknowledgment that “[w]e do not have such data to support OxyContin
4 promotion,” Purdue ran a full-page ad for OxyContin in the *Journal of the American Medical*
5 *Association*, proclaiming, “There Can Be Life With Relief,” and showing a man happily fly-fishing
6 alongside his grandson, implying that OxyContin would help users’ function. This ad earned a
7 warning letter from the FDA, which admonished: “It is particularly disturbing that your November
8 ad would tout ‘Life With Relief’ yet fail to warn that patients can die from taking OxyContin.”¹¹⁰
9

10 323. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its*
11 *Management*, which claimed that “multiple clinical studies” have shown that opioids are effective in
12 improving daily function, psychological health, and health-related quality of life for chronic pain
13 patients. But the article cited as support for this in fact stated the contrary, noting the absence of
14 long-term studies and concluding that, “[f]or functional outcomes, the other analgesics were
15 significantly more effective than were opioids.”
16

17 324. A series of medical journal advertisements for OxyContin in 2012 presented “Pain
18 Vignettes” – case studies featuring patients with pain conditions persisting over several months –
19 that implied functional improvement. For example, one advertisement described a “writer with
20 osteoarthritis of the hands” and implied that OxyContin would help him work more effectively.
21

22 325. Similarly, since at least May of 2011, Endo has distributed and made available on its
23 website, *www.Opana.com*, a pamphlet promoting Opana ER with photographs depicting patients
24 with physically demanding jobs like those of a construction worker or chef, misleadingly implying
25 that the drug would provide long-term pain relief and functional improvement.

26 ¹⁰⁹ Barry Meier, *Pain Killer: A “Wonder” Drug’s Trail of Addiction and Death* 281 (Rodale 2003)

27 ¹¹⁰ Chris Adams, *FDA Orders Purdue Pharma to Pull Its OxyContin Ads*, Wall St. J. (Jan. 23, 2003,
28 12:01am), <https://www.wsj.com/articles/SB1043259665976915824>.

1 326. As noted above, Janssen sponsored and edited a patient education guide entitled
2 *Finding Relief: Pain Management for Older Adults* (2009), which states as “a fact” that “opioids
3 may make it easier for people to live normally.” This guide features a man playing golf on the cover
4 and lists examples of expected functional improvement from opioids, like sleeping through the night,
5 returning to work, recreation, sex, walking, and climbing stairs. It assures patients that, “[u]sed
6 properly, opioid medications can make it possible for people with chronic pain to ‘return to
7 normal.’” Similarly, *Responsible Opioid Prescribing* (2007), sponsored and distributed by Teva,
8 Endo, and Purdue, taught that relief of pain by opioids, by itself, improved patients’ function. The
9 book remains for sale online.

11 327. In addition, Janssen’s *Let’s Talk Pain* website featured a video interview, which was
12 edited by Janssen personnel, claiming that opioids were what allowed a patient to “continue to
13 function,” falsely implying that her experience would be representative.

15 328. APF’s *Treatment Options: A Guide for People Living with Pain* (2007), sponsored by
16 Purdue and Cephalon, counseled patients that opioids “give [pain patients] a quality of life [they]
17 deserve.” The guide was available online until APF shut its doors in May 2012.

18 329. Endo’s NIPC website, www.PainKnowledge.com, claimed that with opioids, “your
19 level of function should improve; you may find you are now able to participate in activities of daily
20 living, such as work and hobbies, that you were not able to enjoy when your pain was worse.” In
21 addition to “improved function,” the website touted improved quality of life as a benefit of opioid
22 therapy. The grant request that Endo approved for this project specifically indicated NIPC’s intent
23 to make claims of functional improvement.

25 330. Endo was the sole sponsor, through NIPC, of a series of CMEs titled *Persistent Pain*
26 *in the Older Patient*, which claimed that chronic opioid therapy has been “shown to reduce pain and
27 improve depressive symptoms and cognitive functioning.” The CME was disseminated via webcast.

1 331. Mallinckrodt’s website, in a section on responsible use of opioids, claims that “[t]he
2 effective pain management offered by our medicines helps enable patients to stay in the workplace,
3 enjoy interactions with family and friends, and remain an active member of society.”¹¹¹

4 332. The Marketing Defendants’ claims that long-term use of opioids improves patient
5 function and quality of life are unsupported by clinical evidence. There are no controlled studies of
6 the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients’ pain and
7 function long term. The FDA, for years, has made clear through warning letters to manufacturers the
8 lack of evidence for claims that the use of opioids for chronic pain improves patients’ function and
9 quality of life.¹¹² Based upon a review of the existing scientific evidence, the CDC Guideline
10 concluded that “there is no good evidence that opioids improve pain or function with long-term
11 use.”¹¹³
12

13 333. Consistent with the CDC’s findings, substantial evidence exists demonstrating that
14 opioid drugs are ineffective for the treatment of chronic pain and worsen patients’ health. For
15 example, a 2006 study-of-studies found that opioids as a class did not demonstrate improvement in
16 functional outcomes over other non-addicting treatments. The few longer term studies of opioid use
17 had “consistently poor results,” and “several studies have show[n] that [using] opioids for chronic
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19
20 ¹¹¹ Mallinckrodt Pharmaceuticals, *Responsible Use*, <http://www.mallinckrodt.com/corporate-responsibility/responsible-use> (last visited Mar. 12, 2020).

21 ¹¹² The FDA has warned other drugmakers that claims of improved function and quality of life were
22 misleading. See Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., &
23 Commc’ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010) (rejecting claims that
24 Actavis’s opioid, Kadian, had an “overall positive impact on a patient’s work, physical and mental
25 functioning, daily activities, or enjoyment of life”); Warning Letter from Thomas Abrams, Dir.,
26 FDA Div. of Mktg., Adver., & Commc’ns, to Brian A. Markison, Chairman, President and Chief
Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008) (finding the claim that “patients
who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall
function, social function, and ability to perform daily activities . . . has not been demonstrated by
substantial evidence or substantial clinical experience”). The FDA’s warning letters were available
to Defendants on the FDA website.

27 ¹¹³ Deborah Dowell, M.D., *et al.*, *CDC Guideline for Prescribing Opioids for Chronic Pain –*
28 *United States 2016*, 65(1) Morbidity & Mortality Wkly. Rep. 1, 20 (Mar. 18, 2016).

1 pain may actually worsen pain and functioning,”¹¹⁴ along with general health, mental health, and
 2 social function. Over time, even high doses of potent opioids often fail to control pain, and patients
 3 exposed to such doses are unable to function normally.

4 334. The available evidence indicates opioids may worsen patients’ health and pain.
 5 Increased duration of opioid use is strongly associated with increased prevalence of mental health
 6 disorders (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased
 7 psychological distress, and greater health care utilization. The CDC Guideline concluded that,
 8 “[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic
 9 pain are uncertain, risks associated with long-term opioid use are clearer and significant.”¹¹⁵
 10 According to the CDC, “for the vast majority of patients, the known, serious, and too-often-fatal
 11 risks far outweigh the unproven and transient benefits [of opioids for chronic pain].”¹¹⁶
 12

13 335. As one pain specialist observed, “opioids may work acceptably well for a while, but
 14 over the long term, function generally declines, as does general health, mental health, and social
 15 functioning. Over time, even high doses of potent opioids often fail to control pain, and these
 16 patients are unable to function normally.”¹¹⁷ In fact, research such as a 2008 study in the journal
 17 *Spine* has shown that pain sufferers prescribed opioids over the long term suffered addiction that
 18 made them more likely to be disabled and unable to work.¹¹⁸ Another study demonstrated that
 19
 20

21 ¹¹⁴ Thomas R. Frieden and Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-*
 22 *Prescribing Guideline*, New Eng. J. of Med. 1503 (Apr. 21, 2016).

23 ¹¹⁵ Deborah Dowell, M.D., *et al.*, *CDC Guideline for Prescribing Opioids for Chronic Pain –*
United States 2016, 65(1) Morbidity & Mortality Wkly. Rep. 1, 2, 18 (Mar. 18, 2016).

24 ¹¹⁶ Thomas R. Frieden and Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-*
 25 *Prescribing Guideline*, New Eng. J. of Med. 1503 (Apr. 21, 2016).

26 ¹¹⁷ Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009),
 27 <http://www.nbcmcs.org/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse.aspx?pageid=144&tabid=747>.

28 ¹¹⁸ Jeffrey Dersh, *et al.*, *Prescription Opioid Dependence is Associated With Poorer Outcomes in*
Disabling Spinal Disorders, 33(20) *Spine* 2219-27 (Sept. 15, 2008).

1 injured workers who received a prescription opioid for more than 7 days during the first 6 weeks
 2 after the injury were 2.2 times more likely to remain on work disability a year later than workers
 3 with similar injuries who received no opioids at all.¹¹⁹

4
 5 **g. Falsehood No. 7: Alternative Forms of Pain Relief Pose
 Greater Risks than Opioids**

6 336. In materials they produced, sponsored or controlled, the Marketing Defendants
 7 omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing
 8 products so that prescribers and patients would favor opioids over other therapies such as over-the-
 9 counter acetaminophen or over-the-counter or prescription NSAIDs.

10 337. For example, in addition to failing to disclose in promotional materials the risks of
 11 addiction, overdose, and death, the Marketing Defendants routinely ignored the risks of
 12 hyperalgesia, a “known serious risk associated with chronic opioid analgesic therapy in which the
 13 patient becomes more sensitive to certain painful stimuli over time”;¹²⁰ hormonal dysfunction;¹²¹
 14 decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures
 15 in the elderly;¹²² neonatal abstinence syndrome (when an infant exposed to opioids prenatally suffers
 16 withdrawal after birth); and potentially fatal interactions with alcohol or with benzodiazepines,
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 18
 19
 20

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 22 ¹¹⁹ GM Franklin, BD Stover, JA Turner, D Fulton-Kehoe, TM Wickizer, *Early Opioid Prescription
 and Subsequent Disability Among Workers With Back Injuries: The Disability Risk Identification
 Study Cohort*, 33(2) Spine 199, 201-202 (Jan. 15, 2008).

23
 24 ¹²⁰ Letter from Janet Woodcock, M.D., Dir. of Ctr. for Drug Eval. & Res., to Andrew Kolodny,
 M.D., Pres. of Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818
 (Sept. 10, 2013).

25
 26 ¹²¹ H.W. Daniell, *Hypogonadism in Men Consuming Sustained-Action Oral Opioids*, 3(5) J. Pain
 377, 377-84 (2001).

27
 28 ¹²² Bernhard M. Kuschel, *The Risk of Fall Injury in Relation to Commonly Prescribed Medications
 Among Older People – A Swedish Case-Control Study*, 25(3) Eur. J. Pub. H. 527, 527-32 (July 31,
 2014).

1 which are used to treat anxiety and may be co-prescribed with opioids, particularly to veterans
 2 suffering from pain.¹²³

3 338. APF's *Treatment Options: A Guide for People Living with Pain*, sponsored by Purdue
 4 and Cephalon, warned that risks of NSAIDs increase if "taken for more than a period of months,"
 5 with no corresponding warning about opioids. The publication falsely attributed 10,000 to 20,000
 6 deaths annually to NSAID overdoses, when the figure is closer to 3,200.

8 339. Janssen sponsored *Finding Relief: Pain Management for Older Adults* (2009), which
 9 listed dose limitations as "disadvantages" of other pain medicines but omitted any discussion of risks
 10 of increased doses from opioids. *Finding Relief* described the advantages and disadvantages of
 11 NSAIDs on one page, and the "myths/facts" of opioids on the facing page. The disadvantages of
 12 NSAIDs are described as involving "stomach upset or bleeding," "kidney or liver damage if taken at
 13 high doses or for a long time," "adverse reactions in people with asthma," and "can increase the risk
 14 of heart attack and stroke." The only adverse effects of opioids listed are "upset stomach or
 15 sleepiness," which the brochure claims will go away, and constipation.

17 340. Endo's NIPC website, www.Painknowledge.com, contained a flyer called *Pain:*
 18 *Opioid Therapy*. This publication listed opioids' adverse effects but with significant omissions,
 19 including hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance,
 20 dependence, addiction, and death.

22 341. As another example, the Endo-sponsored CME put on by NIPC, *Persistent Pain in*
 23 *the Older Adult*, discussed above, counseled that acetaminophen should be used only short term and
 24 included five slides on the FDA's restrictions on acetaminophen and its adverse effects, including
 25 severe liver injury and anaphylaxis (shock). In contrast, the CME downplayed the risk of opioids,

27 ¹²³ Karen H. Seal *et al.*, *Association of Mental Health Disorders With Prescription Opioids and*
 28 *High-Risk Opioids in US Veterans of Iraq and Afghanistan*, 307(9) J. of Am. Med. Assoc. 940, 940-
 47 (2012).

1 claiming opioids have “possibly less potential for abuse than in younger patients,” and did not list
 2 overdose among the adverse effects. Some of those misrepresentations are described above; others
 3 are laid out below.

4 342. In April 2007, Endo sponsored an article aimed at prescribers, published in *Pain*
 5 *Medicine News*, titled *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*.¹²⁴
 6

7 The article asserted:

8 Opioids represent a highly effective but controversial and often
 9 misunderstood class of analgesic medications for controlling both chronic and acute
 10 pain. The phenomenon of tolerance to opioids – the gradual waning of relief at a
 11 given dose – and fears of abuse, diversion, and misuse of these medications by
 12 patients have led many clinicians to be wary of prescribing these drugs, and/or to
 13 restrict dosages to levels that may be insufficient to provide meaningful relief.¹²⁵

14 343. To help allay these concerns, Endo emphasized the risks of NSAIDs as an alternative
 15 to opioids. The article included a case study that focused on the danger of extended use of NSAIDs,
 16 including that the subject was hospitalized with a massive upper gastrointestinal bleed believed to
 17 have resulted from his protracted NSAID use. In contrast, the article did not provide the same detail
 18 concerning the serious side effects associated with opioids.

19 344. Additionally, Purdue acting with Endo sponsored *Overview of Management Options*,
 20 a CME issued by the AMA in 2003, 2007, 2010, and 2013. The 2013 version remains available for
 21 CME credit. The CME taught that NSAIDs and other drugs, but not opioids, are unsafe at high
 22 doses.

23 345. As a result of the Marketing Defendants’ deceptive promotion of opioids over safer
 24 and more effective drugs, opioid prescriptions increased even as the percentage of patients visiting a
 25 doctor for pain remained constant. A study of 7.8 million doctor visits between 2000 and 2010

26 ¹²⁴ Charles E. Argoff, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*,
 27 *Pain Med. News* (Apr. 2007), http://www.painmedicineneeds.com/download/BtoB_Opana_WM.pdf.

28 ¹²⁵ *Id.* at 1.

1 found that opioid prescriptions increased from 11.3% to 19.6% of visits, as NSAID and
2 acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline in NSAID
3 prescribing.

4 **h. Falsehood No. 8: OxyContin Provides 12 Hours of Pain**
5 **Relief**

6 346. Purdue also dangerously misled doctors and patients about OxyContin's duration and
7 onset of action, making the knowingly false claim that OxyContin would provide 12 hours of pain
8 relief for most patients. As laid out below, Purdue made this claim for two reasons. First, it
9 provides the basis for both Purdue's patent and its market niche, allowing it to both protect and
10 differentiate itself from competitors. Second, it allowed Purdue to imply or state outright that
11 OxyContin had a more even, stable release mechanism that avoided peaks and valleys and therefore
12 the rush that fostered addiction and attracted abusers.

13
14 347. Purdue promotes OxyContin as an extended-release opioid, but the oxycodone does
15 not enter the body at a linear rate. OxyContin works by releasing a greater proportion of oxycodone
16 into the body upon administration, and the release gradually tapers, as illustrated in the following
17 chart, which was apparently adapted from Purdue's own sales materials:
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OxyContin PI Figure, Linear y-axis

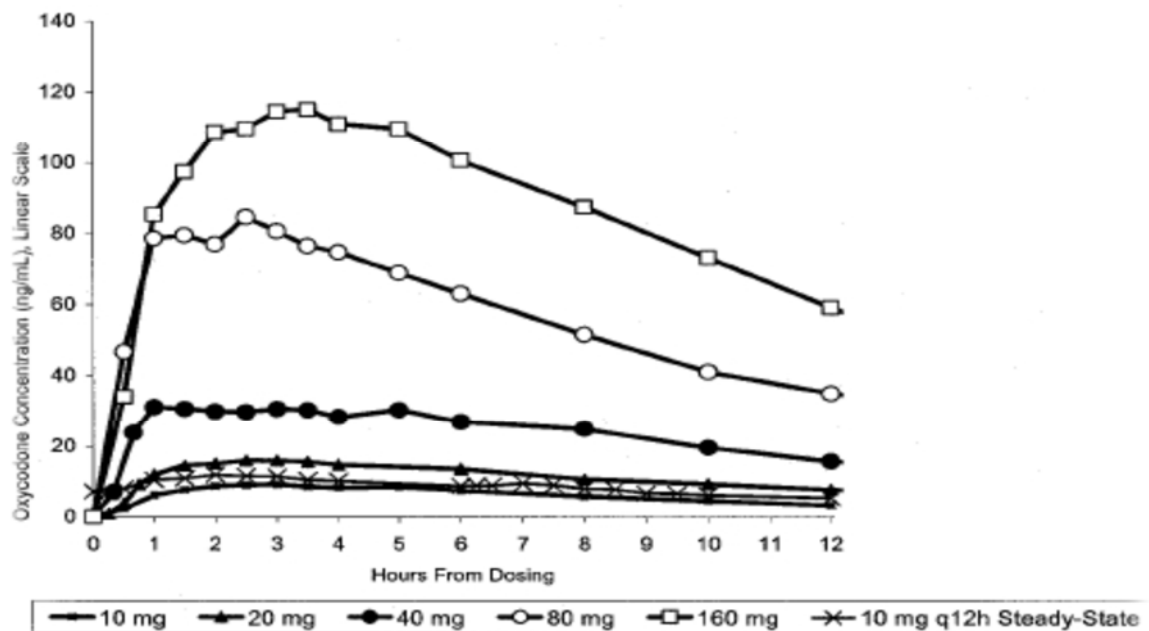


Figure 1

348. The reduced release of the drug over time means that the oxycodone no longer provides the same level of pain relief; as a result, in many patients, OxyContin does not last the 12 hours for which Purdue promotes it – a fact that Purdue has known at all times relevant to this action.

349. OxyContin tablets provide an initial absorption of approximately 40% of the active medicine. This has a two-fold effect. First, the initial rush of nearly half of the powerful opioid triggers a powerful psychological response. OxyContin thus behaves more like an immediate-release opioid, which Purdue itself once claimed was more addicting in its original 1995 FDA-approved drug label. Second, the initial burst of oxycodone means that there is less of the drug at the end of the dosing period, which results in the drug not lasting for a full 12 hours and precipitates withdrawal symptoms in patients, a phenomenon known as “end of dose” failure. (The FDA found

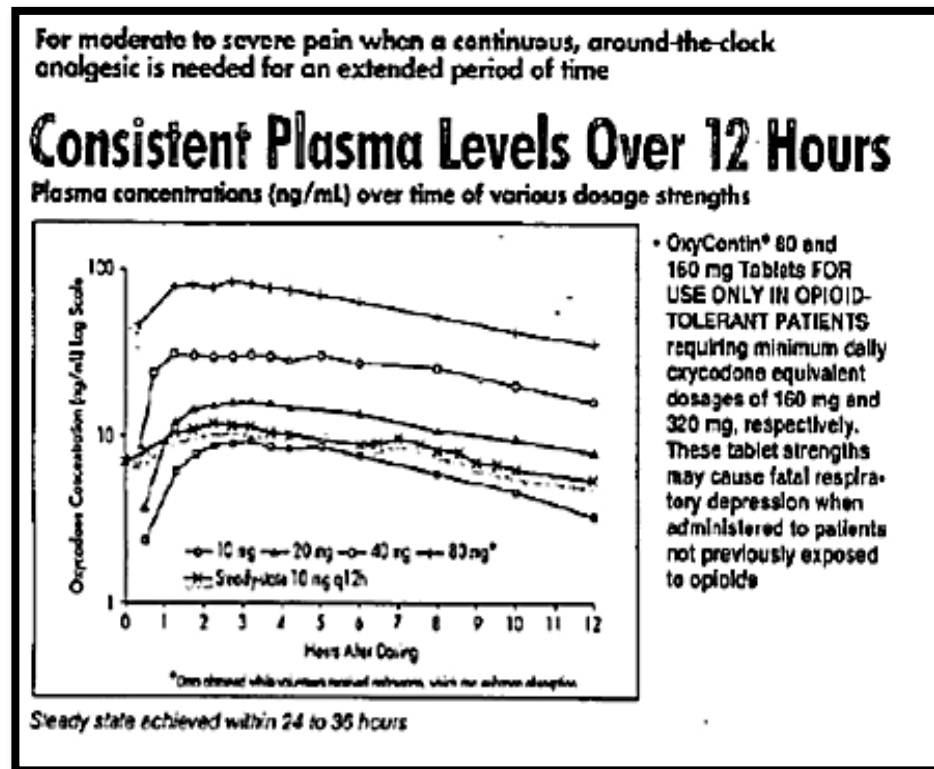
1 in 2008 that a “substantial number” of chronic pain patients will experience end-of-dose failure with
2 OxyContin.)

3 350. End-of-dose failure renders OxyContin even more dangerous because patients begin
4 to experience withdrawal symptoms, followed by a euphoric rush with their next dose – a cycle that
5 fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the
6 Washington University School of Medicine in St. Louis, has called OxyContin’s 12-hour dosing “the
7 perfect recipe for addiction.”¹²⁶ Many patients will exacerbate this cycle by taking their next dose
8 ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of
9 opioids they are taking.
10

11 351. It was Purdue’s decision to submit OxyContin for approval with 12-hour dosing.
12 While the OxyContin label indicates that “[t]here are no well-controlled clinical studies evaluating
13 the safety and efficacy with dosing more frequently than every 12 hours,” that is because Purdue has
14 conducted no such studies.
15

16 352. Purdue nevertheless has falsely promoted OxyContin as if it were effective for a full
17 12 hours. Its advertising in 2000 included claims that OxyContin provides “Consistent Plasma
18 Levels Over 12 Hours.” That claim was accompanied by a chart, mirroring the chart on the previous
19 page. However, this version of the chart deceptively minimized the rate of end-of-dose failure by
20 depicting 10 mg in a way that it appeared to be half of 100 mg in the table’s y-axis. That chart,
21 shown below, depicts the same information as the chart above, but does so in a way that makes the
22 absorption rate appear more consistent:
23
24
25
26

27 ¹²⁶ Harriet Ryan, *et al.*, “‘You Want a Description of Hell?’ OxyContin’s 12-Hour Problem,” L.A.
28 Times (May 5, 2016), <http://www.latimes.com/projects/oxycontin-part1/>.



353. Purdue's 12-hour messaging was key to its competitive advantage over short-acting opioids that required patients to wake in the middle of the night to take their pills. Purdue advertisements also emphasized "Q12h" dosing. These include an advertisement in the February 2005 *Journal of Pain* and 2006 *Clinical Journal of Pain* featuring an OxyContin logo with two pill cups, reinforcing the twice-a-day message. A Purdue memo to the OxyContin launch team stated that "OxyContin's positioning statement is 'all of the analgesic efficacy of immediate-release oxycodone, with convenient q12h dosing,'" and further that "[t]he convenience of q12h dosing was emphasized as the most important benefit."¹²⁷

354. In keeping with this positioning statement, a Purdue regional manager emphasized in a 1996 sales strategy memo that representatives should "convinc[e] the physician that there is no need" for prescribing OxyContin in shorter intervals than the recommended 12-hour interval, and

¹²⁷ Memorandum from Lydia Johnson, Marketing Executive at Purdue, to members of OxyContin Launch Team (Apr. 4, 1995), <http://documents.latimes.com/oxycontin-launch-1995/> (last updated May 5, 2016).

1 instead the solution is prescribing higher doses.¹²⁸ One sales manager instructed her team that
 2 anything shorter than 12-hour dosing ““needs to be nipped in the bud, NOW!!””¹²⁹

3 355. Purdue executives therefore maintained the messaging of 12-hour dosing even when
 4 many reports surfaced that OxyContin did not last 12 hours. Instead of acknowledging a need for
 5 more frequent dosing, Purdue instructed its representatives to push higher strength pills, even though
 6 higher dosing carries its own risks, as noted above. It also means that patients will experience higher
 7 highs and lower lows, increasing their craving for their next pill. (Urging higher doses to avoid end-
 8 of-dose failure is like advising a pilot to avoid a crash by flying higher.) Nationwide, based on an
 9 analysis by the *Los Angeles Times*, more than 52% of patients taking OxyContin longer than three
 10 months are on doses greater than 60 milligrams per day – which converts to the 90 MME that the
 11 CDC Guideline urges prescribers to “avoid” or “carefully justify.”¹³⁰
 12

13 356. That OxyContin did not provide pain relief for a full 12 hours was known to Purdue,
 14 and Purdue’s competitors, but was not disclosed to prescribers. Purdue’s knowledge of some pain
 15 specialists’ tendency to prescribe OxyContin three times per day instead of two was set out in
 16 Purdue’s internal documents as early as 1999 and is apparent from MedWatch Adverse Event reports
 17 for OxyContin.
 18

19 357. Even Purdue’s competitor, Endo, was aware of the problem; Endo attempted to
 20 position its Opana ER drug as offering “durable” pain relief, which Endo understood to suggest a
 21 contrast to OxyContin. Opana ER advisory board meetings featured pain specialists citing lack of
 22

23
 24 ¹²⁸ Letter from Windell Fisher, Purdue Regional Manager, to B. Gergely, Purdue Employee (Nov. 7,
 25 1996), <http://documents.latimes.com/sales-manager-on-12-hour-dosing-1996/> (last updated May 5,
 2016).

26 ¹²⁹ Harriet Ryan, *et al.*, ““You Want a Description of Hell?’ OxyContin’s 12-Hour Problem,” *L.A.*
 27 *Times* (May 5, 2016), <http://www.latimes.com/projects/oxycontin-part1/>.

28 ¹³⁰ Deborah Dowell, M.D., *et al.*, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States 2016*, 65(1) *Morbidity & Mortality Wkly. Rep.* 16 (Mar. 18, 2016).

1 12-hour dosing as a disadvantage of OxyContin. Endo even ran advertisements for Opana ER
 2 referring to “real” 12-hour dosing.

3 358. Purdue’s failure to disclose the prevalence of end-of-dose failure meant that
 4 prescribers were misinformed about the advantages of OxyContin in a manner that preserved
 5 Purdue’s competitive advantage and profits, at the expense of patients, who were placed at greater
 6 risk of overdose, addiction, and other adverse effects.
 7

8 **i. Falsehood No. 9: New Formulations of Certain Opioids**
 9 **Successfully Deter Abuse**

10 359. Rather than take the widespread abuse of and addiction to opioids as a reason to cease
 11 their untruthful marketing efforts, Marketing Defendants Purdue and Endo seized them as a
 12 competitive opportunity. These companies developed and oversold “abuse-deterrent formulation”
 13 (“ADF”) opioids as a solution to opioid abuse and as a reason that doctors could continue to safely
 14 prescribe their opioids, as well as an advantage of these expensive branded drugs over other opioids.
 15 Purdue’s and Endo’s false and misleading marketing of the benefits of their ADF opioids preserved
 16 and expanded their sales and falsely reassured prescribers, thereby prolonging the opioid epidemic.
 17 Other Marketing Defendants, including Actavis and Mallinckrodt, also promoted their branded
 18 opioids as formulated to be less addictive or less subject to abuse than other opioids.
 19

20 360. The CDC Guideline confirms that “[n]o studies” support the notion that “abuse-
 21 deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse,” noting that
 22 the technologies “do not prevent opioid abuse through oral intake, the most common route of opioid
 23 abuse, and can still be abused by non-oral routes.” Tom Frieden, the former Director of the CDC,
 24 reported that his staff could not find “any evidence showing the updated [ADF opioids] actually
 25 reduce rates of addiction, overdoses, or deaths.”
 26
 27
 28

(1) Purdue's Deceptive Marketing of Reformulated OxyContin and Hysingla ER

361. Reformulated ADF OxyContin was approved by the FDA in April 2010. It was not until 2013 that the FDA, in response to a citizen petition filed by Purdue, permitted reference to the abuse-deterrent properties in its label. When Hysingla ER (extended-release hydrocodone) launched in 2014, the product included similar abuse-deterrent properties and limitations. But in the beginning, the FDA made clear the limited claims that could be made about ADF, noting that no evidence supported claims that ADF prevented tampering, oral abuse, or overall rates of abuse.

362. It is unlikely a coincidence that reformulated OxyContin was introduced shortly before generic versions of OxyContin were to become available, threatening to erode Purdue's market share and the price it could charge. Purdue nonetheless touted its introduction of ADF opioids as evidence of its good corporate citizenship and commitment to address the opioid crisis.

363. Despite its self-proclaimed good intention, Purdue merely incorporated its generally deceptive tactics with respect to ADF. Purdue sales representatives regularly overstated and misstated the evidence for and impact of the abuse-deterrent features of these opioids. Specifically, Purdue sales representatives:

(a) claimed that Purdue's ADF opioids prevent tampering and that its ADFs could not be crushed or snorted;

(b) claimed that Purdue's ADF opioids reduce opioid abuse and diversion;

(c) asserted or suggested that its ADF opioids are non-addictive or less addictive;

(d) asserted or suggested that Purdue's ADF opioids are safer than other opioids, could not be abused or tampered with, and were not sought out for diversion; and

(e) failed to disclose that Purdue's ADF opioids do not impact oral abuse or misuse.

1 364. If pressed, Purdue acknowledged that perhaps some “extreme” patients might still
2 abuse the drug, but claimed the abuse-deterrent features protect the majority of patients. These
3 misrepresentations and omissions are misleading and contrary to Purdue’s ADF labels, Purdue’s own
4 information, and publicly available data.

5 365. Purdue knew or should have known that reformulated OxyContin is not more tamper-
6 resistant than the original OxyContin and is still regularly tampered with and abused.

7 366. In 2009, the FDA noted in permitting ADF labeling that “the tamper-resistant
8 properties will have no effect on abuse by the oral route (the most common mode of abuse).” In the
9 2012 medical office review of Purdue’s application to include an abuse-deterrence claim in its label
10 for OxyContin, the FDA noted that the overwhelming majority of deaths linked to OxyContin were
11 associated with oral consumption, and that only 2% of deaths were associated with recent injection
12 and only 0.2% with snorting the drug.

13 367. The FDA’s Director of the Division of Epidemiology stated in September 2015 that
14 no data that she had seen suggested the reformulation of OxyContin “actually made a reduction in
15 abuse,” between continued oral abuse, shifts to injection of other drugs (including heroin), and defeat
16 of the ADF mechanism. Even Purdue’s own funded research shows that half of OxyContin abusers
17 continued to abuse OxyContin orally after the reformulation rather than shift to other drugs.

18 368. A 2013 article presented by Purdue employees based on review of data from poison
19 control centers, concluded that ADF OxyContin can reduce abuse, but it ignored important negative
20 findings. The study revealed that abuse merely shifted to other drugs and that, when the actual
21 incidence of harmful exposures was calculated, there were *more* harmful exposures to opioids after
22 the reformulation of OxyContin. In short, the article deceptively emphasized the advantages and
23 ignored the disadvantages of ADF OxyContin.

1 369. Websites and message boards used by drug abusers, such as bluelight.org and
 2 reddit.com, report a variety of ways to tamper with OxyContin and Hysingla ER, including through
 3 grinding, microwaving then freezing, or drinking soda or fruit juice in which a tablet is dissolved.
 4 Purdue has been aware of these methods of abuse for more than a decade.

5 370. One-third of the patients in a 2015 study defeated the ADF mechanism and were able
 6 to continue inhaling or injecting the drug. To the extent that the abuse of Purdue's ADF opioids was
 7 reduced, there was no meaningful reduction in opioid abuse overall, as many users simply shifted to
 8 other opioids such as heroin.

9 371. In 2015, claiming a need to further assess its data, Purdue abruptly withdrew a
 10 supplemental NDA related to reformulated OxyContin one day before the FDA staff was to release
 11 its assessment of the application. The staff review preceded an FDA advisory committee meeting
 12 related to new studies by Purdue "evaluating the misuse and/or abuse of reformulated OxyContin"
 13 and whether those studies "have demonstrated that the reformulated OxyContin product has had a
 14 meaningful impact on abuse."¹³¹ Upon information and belief, Purdue never presented the data to
 15 the FDA because the data would not have supported claims that OxyContin's abuse-deterrent
 16 properties reduced abuse or misuse.
 17

18 372. Despite its own evidence of abuse, and the lack of evidence regarding the benefit of
 19 Purdue's ADF opioids in reducing abuse, Dr. J. David Haddox, the Vice President of Health Policy
 20 for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's ADF opioids are
 21 being abused in large numbers. Purdue's recent advertisements in national newspapers also continue
 22 to claim that its ADF opioids are evidence of its efforts to reduce opioid abuse, continuing to mislead
 23 prescribers, patients, payors, and the public about the efficacy of its actions.
 24
 25

26
 27 ¹³¹ Jill Hartzler Warner, Assoc. Comm'r for Special Med. Programs, *Joint Meeting of the Drug*
 28 *Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products*
Advisory Committee; Notice of Meeting, 80(103) Fed. Reg. 30686, 30686 (May 29, 2015).

(2) Endo's Deceptive Marketing of Reformulated Opana ER

373. As the expiration of its patent exclusivity for Opana ER neared, Endo also made abuse deterrence a key to its marketing strategy.

374. Opana ER was particularly likely to be tampered with and abused. That is because Opana ER has lower "bioavailability" than other opioids, meaning that the active pharmaceutical ingredient (the "API" or opioid) does not absorb into the bloodstream as rapidly as other opioids when taken orally. Additionally, when swallowed whole, the extended-release mechanism remains intact, so that only 10% of Opana ER's API is released into the patient's bloodstream relative to injection; when it is taken intranasally, that rate increases to 43%. The larger gap between bioavailability when consumed orally versus snorting or injection, the greater the incentive for users to manipulate the drug's means of administration.

375. Endo knew by July 2011 that "some newer statistics around abuse and diversion are not favorable to our product."

376. In December 2011, Endo obtained approval for a new formulation of Opana ER that added a hard coating that the company claimed made it crush-resistant.

377. Even prior to its approval, the FDA had advised Endo that it could not market the new Opana ER as abuse-deterrent. The FDA found that such promotional claims "may provide a false sense of security since the product may be chewed and ground for subsequent abuse." In other words, Opana ER was still crushable. Indeed, Endo's own studies dating from 2009 and 2010 showed that Opana ER could be crushed and ground, and, in its correspondence with the FDA, Endo admitted that "[i]t has not been established that this new formulation of Opana ER is less subject to misuse, abuse, diversion, overdose, or addiction."

378. Further, a January 4, 2011 FDA Discipline Review letter made clear to Endo that "[t]he totality of these claims and presentations suggest that, as a result of its new formulation,

1 Opana ER offers a therapeutic advantage over the original formulation when this has not been
2 demonstrated by substantial evidence or substantial clinical experience. In addition these claims
3 misleadingly minimize the risks associated with Opana ER by suggesting that the new formulation's
4 'INTAC' technology confers some form of abuse-deterrence properties when this has not been
5 demonstrated by substantial evidence." The FDA acknowledged that while there is "evidence to
6 support some limited improvement" provided by the new coating, it would not let Endo promote any
7 benefit because "there are several limitations to this data." Also, Endo was required to add language
8 to its label specifically indicating that "Opana ER tablets may be abused by crushing, chewing,
9 snorting, or injecting the product. These practices will result in less controlled delivery of the opioid
10 and pose a significant risk to the abuser that could result in overdose and death."

12 379. The FDA expressed similar concerns in nearly identical language in a May 7, 2012
13 letter to Endo responding to a February 2, 2012 "request . . . for comments on a launch Draft
14 Professional Detail Aid . . . for Opana ER." The FDA's May 2012 letter also includes a full two
15 pages of comments regarding "[o]missions of material facts" from Endo's promotional materials.

17 380. Endo consciously chose not to do any post-approval studies that might satisfy the
18 FDA. According to internal documents, the company decided that by the time its studies would be
19 done, generics would be on the market and "any advantages for commercials will have disappeared."
20 However, this lack of evidence did not deter Endo from marketing Opana ER as an ADF while its
21 commercial window remained open.

23 381. Nonetheless, in August of 2012, Endo submitted a citizen petition asking the FDA for
24 permission to change its label to indicate that Opana ER was abuse-resistant, both in that it was less
25 able to be crushed and snorted and that it was resistant to injection by syringe. Borrowing a page
26 from Purdue's playbook, Endo announced it would withdraw original Opana ER from the market
27
28

1 and sought a determination that its decision was made for safety reasons (its lack of abuse
2 deterrence), which would prevent generic copies of original Opana ER.

3 382. Endo then sued the FDA, seeking to force expedited consideration of its citizen
4 petition. The court filings confirmed Endo's true motives: in a declaration submitted with its
5 lawsuit, Endo's chief operating officer indicated that a generic version of Opana ER would decrease
6 the company's revenue by up to \$135 million per year. Endo also claimed that if the FDA did not
7 block generic competition, \$125 million, which Endo spent on developing the reformulated drug to
8 "promote the public welfare," would be lost.¹³² The FDA responded that "Endo's true interest in
9 expedited FDA consideration stems from business concerns rather than protection of the public
10 health."¹³³

12 383. Despite Endo's purported concern with public safety, not only did Endo continue to
13 distribute original, admittedly unsafe Opana ER for nine months after the reformulated version
14 became available, it declined to recall original Opana ER despite its dangers. In fact, Endo claimed
15 in September 2012 to be "proud" that "almost all remaining inventory" of the original Opana ER had
16 "been utilized."¹³⁴

18 384. In its citizen petition, Endo asserted that redesigned Opana ER had "safety
19 advantages." Endo even relied on its rejected assertion that Opana was less crushable to argue that it
20
21
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24 ¹³² Plf.'s Opp. To Defs.' and Intervenor's Motions to Dismiss and Plf.'s Reply in Supp. of Motion
25 for Prelim. Inj., *Endo Pharm. Inc. v. U.S. Food and Drug Admin., et al.*, No. 1:12-cv-01936 (D.D.C.
Dec. 14, 2012), ECF No. 23 at 20.

26 ¹³³ Defs.' Resp. to the Court's Nov. 30, 2012 Order, *Endo Pharm. Inc. v. U.S. Food and Drug
Admin., et al.*, No. 1:12-cv-01936 (D.D.C. Dec. 3, 2012), ECF No. 9 at 6.

27 ¹³⁴ *Id.*; Endo News Release (Sept. 6, 2012), *Endo Pharm. Inc. v. U.S. Food and Drug Admin., et al.*,
28 No. 1:12-cv-01936 (D.D.C. Dec. 9, 2012), ECF No. 18-4 at 81.

1 developed Opana ER for patient safety reasons and that the new formulation would help, for
 2 example, “where children unintentionally chew the tablets prior to an accidental ingestion.”¹³⁵

3 385. However, in rejecting the petition in a 2013 decision, the FDA found that “study data
 4 show that the reformulated version’s extended-release features can be compromised when subjected
 5 to . . . cutting, grinding, or chewing.” The FDA also determined that “reformulated Opana ER”
 6 could also be “readily prepared for injections” and “more easily injected.” In fact, the FDA warned
 7 that preliminary data – including in Endo’s own studies – suggested that a higher percentage of
 8 reformulated Opana ER abuse is via injection than was the case with the original formulation.
 9

10 386. Meanwhile, in 2012, an internal memorandum to Endo account executives noted that
 11 abuse of Opana ER had “increased significantly” in the wake of the purportedly abuse-deterrent
 12 formulation. In February 2013, Endo received abuse data regarding Opana ER from Inflexxion, Inc.,
 13 which gathers information from substance abusers entering treatment and reviews abuse-focused
 14 internet discussions, that confirmed continued abuse, particularly by injection.
 15

16 387. In 2009, only 3% of Opana ER abuse was by intravenous means. After the
 17 reformulation, injection of Opana ER increased by more than 500%. Endo’s own data, presented in
 18 2014, found that, between October 2012 and March 2014, 64% of abusers of Opana ER did so by
 19 injection, compared with 36% for the old formulation.¹³⁶ The transition into injection of Opana ER
 20 made the drug even less safe than the original formulation. Injection carries risks of HIV, Hepatitis
 21 C, and, in reformulated Opana ER’s specific case, the blood-clotting disorder thrombotic
 22 thrombocytopenic purpura (“TTP”), which can cause kidney failure.
 23

24
 25 ¹³⁵ Citizen Petition, FDA Docket 2012-8-0895, at 5 (Aug. 10, 2012)
<https://www.documentcloud.org/documents/2086687-endo-pharmaceuticals-inc-cutter-petition.html>.

26 ¹³⁶ Theresa Cassidy *et al.*, *The Changing Abuse Ecology: Implications for Evaluating the Abuse*
 27 *Pattern of Extended-Release Oxymorphone and Abuse-Deterrent Opioid Formulations*, Pain Week
 28 Abstract 2014, <https://ibhsolutions.com/blog/changing-abuse-ecology-extended-release-oxymorphone/>.

1 388. Publicly, Endo sought to marginalize the problem. On a 2013 call with investors,
2 when asked about an outbreak of TTP in Tennessee from injecting Opana ER, Endo sought to limit
3 its import by assigning it to “a very, very distinct area of the country.”

4 389. Despite its knowledge that Opana ER was widely abused and injected, Endo marketed
5 the drug as tamper resistant and abuse deterrent. Upon information and belief, based on the
6 company’s detailing elsewhere, Endo sales representatives informed doctors that Opana ER was
7 abuse deterrent, could not be tampered with, and was safe. In addition, sales representatives did not
8 disclose evidence that Opana was easier to abuse intravenously and, if pressed by prescribers,
9 claimed that while outlier patients might find a way to abuse the drug, most would be protected.

10 390. A review of national surveys of prescribers regarding their “take-aways” from
11 pharmaceutical detailing confirms that prescribers remember being told Opana ER was tamper
12 resistant. Endo also tracked messages that doctors took from its in-person marketing. Among the
13 advantages of Opana ER, according to participating doctors, was its “low abuse potential.” An
14 internal Endo document also notes that market research showed that “[l]ow abuse potential continues
15 as the primary factor influencing physicians’ anticipated increase in use of Opana ER over the next 6
16 months.”

17 391. In its written materials, Endo marketed Opana ER as having been designed to be
18 crush resistant, knowing that this would (falsely) imply that Opana ER actually was crush resistant
19 and that this crush-resistant quality would make Opana ER less likely to be abused. For example, a
20 June 14, 2012 Endo press release announced “the completion of the company’s transition of its
21 Opana ER franchise to the new formulation designed to be crush resistant.”

22 392. The press release further stated that: “We firmly believe that the new formulation of
23 Opana ER, coupled with our long-term commitment to awareness and education around appropriate
24 use of opioids will benefit patients, physicians and payers.” The press release described the old
25

1 formulation of Opana as subject to abuse and misuse, but failed to disclose the absence of evidence
 2 that reformulated Opana was any better. In September 2012, another Endo press release stressed that
 3 reformulated Opana ER employed “INTAC Technology” and continued to describe the drug as
 4 “designed to be crush-resistant.”

5
 6 393. Similarly, journal advertisements that appeared in April 2013 stated Opana ER was
 7 “designed to be crush resistant.” A January 2013 article in *Pain Medicine News*, based in part on an
 8 Endo press release, described Opana ER as “crush-resistant.” This article was posted on the *Pain*
 9 *Medicine News* website, which was accessible to patients and prescribers.

10 394. Endo, upon information and belief, targeted particular geographies for the redesigned
 11 Opana ER where abuse was most rampant.

12 395. In March 2017, because Opana ER could be “readily prepared for injection” and was
 13 linked to outbreaks of HIV and TTP, an FDA advisory committee recommended that Opana ER be
 14 withdrawn from the market. The FDA adopted this recommendation on June 8, 2017. Endo
 15 announced on July 6, 2017 that it would agree to stop marketing and selling Opana ER. However,
 16 by this point the damage had been done. Even then, Endo continued to insist, falsely, that it “has
 17 taken significant steps over the years to combat misuse and abuse.”

18
 19 **(3) The Other Marketing Defendants’**
 20 **Misrepresentations Regarding Abuse Deterrence**

21 396. A guide for prescribers under Actavis’s copyright deceptively represents that Kadian
 22 is more difficult to abuse and less addictive than other opioids. The guide declares that the “unique
 23 pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine
 24 sulfate for intravenous use by illicit users,” and “KADIAN may be less likely to be abused by health
 25 care providers and illicit users” because of its “[s]low onset of action.” Kadian, however, was not
 26 approved by the FDA as abuse deterrent, and, upon information and belief, Actavis had no studies to
 27 suggest it was.
 28

397. Mallinckrodt promoted both Exalgo (extended-release hydromorphone) and Xartemis XR (oxycodone and acetaminophen) as specifically formulated to reduce abuse. For example, Mallinckrodt’s promotional materials stated that “the physical properties of EXALGO may make it difficult to extract the active ingredient using common forms of physical and chemical tampering, including chewing, crushing and dissolving.”¹³⁷ One member of the FDA’s Controlled Substance Staff, however, noted in 2010 that hydromorphone has “a high abuse potential comparable to oxycodone” and further stated that “we predict that Exalgo will have high levels of abuse and diversion.”¹³⁸

398. With respect to Xartemis XR, Mallinckrodt’s promotional materials stated that “XARTEMIS XR has technology that requires abusers to exert additional effort to extract the active ingredient from the large quantity of inactive and deterrent ingredients.”¹³⁹ In anticipation of Xartemis XR’s approval, Mallinckrodt added 150 to 200 sales representatives to promote it, and CEO Mark Trudeau said the drug could generate “hundreds of millions in revenue.”¹⁴⁰

399. While the Marketing Defendants promote patented technology as the solution to opioid abuse and addiction, none of their “technology” addresses the most common form of abuse – oral ingestion – and their statements regarding abuse-deterrent formulations give the misleading impression that these reformulated opioids can be prescribed safely.

¹³⁷ Press Release, Mallinckrodt, *FDA Approves Mallinckrodt’s EXALGO® (hydromorphone HCl) Extended-Release Tablets 32 mg (CII) for Opioid-Tolerant Patients with Moderate-to-Severe Chronic Pain* (Aug. 27, 2012), <https://www.fiercebiotech.com/biotech/fda-approves-mallinckrodt-s-exalgo-r-hydromorphone-hcl-extended-release-tablets-32-mg-cii>.

¹³⁸ 2010 Meeting Materials, Anesthetic and Analgesic Drug Products Advisory Committee, at 157-58, FDA, <https://wayback.archive-it.org/7993/20170403223634/https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/ucm/193298.htm>.

¹³⁹ Mallinckrodt, *Responsible Use of Opioid Pain Medications* (Mar. 7, 2014).

¹⁴⁰ Samantha Liss, *Mallinckrodt banks on new painkillers for sales*, St. Louis Bus. J. (Dec. 30, 2013), <http://argencapital.com/mallinckrodt-banks-on-new-painkillers-for-sales/>.

1 400. In sum, each of the nine categories of misrepresentations discussed above regarding
 2 the use of opioids to treat chronic pain was not supported by, or was contrary to, the scientific
 3 evidence. In addition, the misrepresentations and omissions set forth above and elsewhere in this
 4 complaint are misleading and contrary to the Marketing Defendants' products' labels.

5
 6 **2. The Marketing Defendants Disseminated Their Misleading
 Messages About Opioids Through Multiple Channels**

7 401. The Marketing Defendants' false marketing campaign not only targeted the medical
 8 community who treat chronic pain, but also patients who experience chronic pain.

9 402. The Marketing Defendants utilized various channels to carry out their marketing
 10 scheme of targeting the medical community and patients with deceptive information about opioids:
 11 (1) "Front Groups" with the appearance of independence from the Marketing Defendants; (2) so-
 12 called "key opinion leaders" ("KOLs"), that is, doctors who were paid by the Marketing Defendants
 13 to promote their pro-opioid message; (3) CME programs controlled and/or funded by the Marketing
 14 Defendants; (4) branded advertising; (5) unbranded advertising; (6) publications; (7) direct, targeted
 15 communications with prescribers by sales representatives or "detailers"; and (8) speakers bureaus
 16 and programs.

17
 18 **a. The Marketing Defendants Directed Front Groups to
 19 Deceptively Promote Opioid Use**

20 403. Patient advocacy groups and professional associations also became vehicles to reach
 21 prescribers, patients, and policymakers. The Marketing Defendants exerted influence and effective
 22 control over the messaging by these groups by providing major funding directly to them, as well as
 23 through KOLs who served on their boards. These "Front Groups" put out patient education
 24 materials, treatment guidelines, and CMEs that supported the use of opioids for chronic pain,
 25 overstated their benefits, and understated their risks.¹⁴¹ Defendants funded these Front Groups in
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 28 ¹⁴¹ U.S. S. Homeland Sec. & Governmental Aff. Comm., Ranking Members' Office, *Fueling an Epidemic* at 3 (Feb. 12, 2018), <https://www.hsdl.org/?abstract&did=808171>.

1 order to ensure supportive messages from these seemingly neutral and credible third parties, and
 2 their funding did, in fact, ensure such supportive messages – often at the expense of their own
 3 constituencies.

4 404. “Patient advocacy organizations and professional societies [like the Front Groups]
 5 play a significant role in shaping health policy debates, setting national guidelines for patient
 6 treatment, raising disease awareness, and educating the public.”¹⁴² “Even small organizations – with
 7 ‘their large numbers and credibility with policymakers and the public’ – have ‘extensive influence in
 8 specific disease areas.’ Larger organizations with extensive funding and outreach capabilities ‘likely
 9 have a substantial effect on policies relevant to their industry sponsors.’”¹⁴³ Indeed, the U.S.
 10 Senate’s report, *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers*
 11 *and Third Party Advocacy Groups*,¹⁴⁴ which arose out of a 2017 Senate investigation, and, drawing
 12 on disclosures from Purdue, Janssen, Insys, and other opioid manufacturers, “provides the first
 13 comprehensive snapshot of the financial connections between opioid manufacturers and advocacy
 14 groups and professional societies operating in the area of opioids policy,”¹⁴⁵ found that the
 15 Marketing Defendants made millions of dollars of contributions to various Front Groups.
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17 405. The Marketing Defendants also “made substantial payments to individual group
 18 executives, staff members, board members, and advisory board members” affiliated with the Front
 19 Groups subject to the Senate Committee’s study.¹⁴⁶
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24 ¹⁴² *Id.* at 2.

25 ¹⁴³ *Id.*

26 ¹⁴⁴ *Id.* at 3.

27 ¹⁴⁵ *Id.* at 1.

28 ¹⁴⁶ *Id.* at 3.

1 406. As the Senate’s *Fueling an Epidemic* report found, the Front Groups “amplified or
 2 issued messages that reinforce industry efforts to promote opioid prescription and use, including
 3 guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain.”¹⁴⁷
 4 They also “lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC
 5 [G]uideline on opioid prescribing, and challenged legal efforts to hold physicians and industry
 6 executives responsible for overprescription and misbranding.”¹⁴⁸

8 407. The Marketing Defendants took an active role in guiding, reviewing, and approving
 9 many of the false and misleading statements issued by the Front Groups, ensuring that Defendants
 10 were consistently in control of their content. By funding, directing, editing, approving, and
 11 distributing these materials, Defendants exercised control over and adopted their false and deceptive
 12 messages and acted in concert with the Front Groups and through the Front Groups to deceptively
 13 promote the use of opioids for the treatment of chronic pain.

15 (1) American Pain Foundation

16 408. The most prominent of the Front Groups was the American Pain Foundation (“APF”).
 17 While APF held itself out as an independent patient advocacy organization, in reality it received
 18 90% of its funding in 2010 from the drug and medical-device industry, including from defendants
 19 Purdue, Endo, Janssen and Cephalon. APF received more than \$10 million in funding from opioid
 20 manufacturers from 2007 until it closed its doors in May 2012. By 2011, APF was entirely
 21 dependent on incoming grants from Purdue, Cephalon, Endo, and others to avoid using its line of
 22 credit. Endo was APF’s largest donor and provided more than half of its \$10 million in funding
 23 from 2007 to 2012.

27 ¹⁴⁷ *Id.* at 12-15.

28 ¹⁴⁸ *Id.* at 12.

1 409. For example, APF published a guide sponsored by Cephalon and Purdue titled
2 *Treatment Options: A Guide for People Living with Pain*, and distributed 17,200 copies of this guide
3 in one year alone, according to its 2007 annual report. This guide contains multiple
4 misrepresentations regarding opioid use, which are discussed below.

5
6 410. APF also developed the National Initiative on Pain Control (“NIPC”), which ran a
7 facially unaffiliated website, *www.PainKnowledge.com*. NIPC promoted itself as an education
8 initiative led by its expert leadership team, including purported experts in the pain management field.
9 NIPC published unaccredited prescriber education programs (accredited programs are reviewed by a
10 third party and must meet certain requirements of independence from pharmaceutical companies),
11 including a series of “dinner dialogues.” But it was Endo that substantially controlled NIPC, by
12 funding NIPC projects, developing, specifying, and reviewing its content, and distributing NIPC
13 materials. Endo’s control of NIPC was such that Endo listed it as one of its “professional education
14 initiative[s]” in a plan Endo submitted to the FDA. Yet Endo’s involvement in NIPC was nowhere
15 disclosed on the website pages describing NIPC or *www.PainKnowledge.com*. Endo estimated it
16 would reach 60,000 prescribers through NIPC.
17

18 411. APF was often called upon to provide “patient representatives” for the Marketing
19 Defendants’ promotional activities, including for Purdue’s “Partners Against Pain” and Janssen’s
20 “Let’s Talk Pain.” Although APF presented itself as a patient advocacy organization, it functioned
21 largely as an advocate for the interests of the Marketing Defendants, not patients. As Purdue told
22 APF in 2001, the basis of a grant to the organization was Purdue’s desire to strategically align its
23 investments in nonprofit organizations that share its business interests.
24

25 412. In practice, APF operated in close collaboration with Defendants, submitting grant
26 proposals seeking to fund activities and publications suggested by Defendants and assisting in
27 marketing projects for Defendants.
28

1 413. This alignment of interests was expressed most forcefully in the fact that Purdue hired
2 APF to provide consulting services on its marketing initiatives. Purdue and APF entered into a
3 “Master Consulting Services Agreement” on September 14, 2011. That agreement gave Purdue
4 substantial rights to control APF’s work related to a specific promotional project. Moreover, based
5 on the assignment of particular Purdue “contacts” for each project and APF’s periodic reporting on
6 their progress, the agreement enabled Purdue to be regularly aware of the misrepresentations APF
7 was disseminating regarding the use of opioids to treat chronic pain in connection with that project.
8 The agreement gave Purdue – but not APF – the right to end the project (and, thus, APF’s funding)
9 for any reason. Even for projects not produced during the terms of this agreement, the agreement
10 demonstrates APF’s lack of independence and its willingness to harness itself to Purdue’s control
11 and commercial interests, which would have carried across all of APF’s work.
12

13 414. APF’s board of directors was largely comprised of doctors who were on the
14 Marketing Defendants’ payrolls, either as consultants or speakers at medical events. The close
15 relationship between APF and the Marketing Defendants demonstrates APF’s clear lack of
16 independence, in its finances, management, and mission, and its willingness to allow the Marketing
17 Defendants to control its activities and messages supports an inference that each defendant that
18 worked with it was able to exercise editorial control over its publications – even when defendants’
19 messages contradicted APF’s internal conclusions. For example, a roundtable convened by APF and
20 funded by Endo also acknowledged the lack of evidence to support chronic opioid therapy. APF’s
21 formal summary of the meeting notes concluded that: “[An] important barrier[] to appropriate opioid
22 management [is] the [l]ack of confirmatory data about the long-term safety and efficacy of opioids in
23 non-cancer chronic pain, amid cumulative clinical evidence.”
24

25 415. In May 2012, the U.S. Senate Finance Committee began looking into APF to
26 determine the links, financial and otherwise, between the organization and the manufacturers of
27
28

1 opioid painkillers. Within days of being targeted by the Senate investigation, APF’s board voted to
 2 dissolve the organization “due to irreparable economic circumstances.” APF then “cease[d] to exist,
 3 effective immediately.” Without support from the Marketing Defendants, to whom APF could no
 4 longer be helpful, APF was no longer financially viable.

5
 6 **(2) American Academy of Pain Medicine and
 American Pain Society**

7 416. The American Academy of Pain Medicine (“AAPM”) and the American Pain Society
 8 (“APS”) are professional medical societies, each of which received substantial funding from
 9 Defendants from 2009 to 2013. In 1997, AAPM issued a “consensus” statement that endorsed
 10 opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids
 11 was low.¹⁴⁹ The Chair of the committee that issued the statement, Dr. J. David Haddox (“Dr.
 12 Haddox”), was at the time a paid speaker for Purdue. The sole consultant to the committee was
 13 Dr. Russell Portenoy, who was also a spokesperson for Purdue. The consensus statement, which
 14 also formed the foundation of the 1998 Guidelines, was published on the AAPM’s website.

15
 16 417. AAPM’s corporate council includes Purdue, Depomed, Teva and other
 17 pharmaceutical companies. AAPM’s past presidents include Dr. Haddox (1998), Dr. Scott Fishman
 18 (“Dr. Fishman”) (2005), Dr. Perry G. Fine (“Dr. Fine”) (2011), and Dr. Lynn R. Webster (“Dr.
 19 Webster”) (2013), all of whose connections to the opioid manufacturers are well documented as set
 20 forth below.
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27 ¹⁴⁹ *The Use of Opioids for the Treatment of Chronic Pain*, APS & AAPM (1997),
 28 <http://www.stgeorgeutah.com/wp-content/uploads/2016/05/OPIOIDES.DOLORCRONICO.pdf>.

1 418. Fishman, who also served as a KOL for the Marketing Defendants, stated that he
 2 would place the organization “at the forefront” of teaching that “the risks of addiction are . . . small
 3 and can be managed.”¹⁵⁰

4 419. AAPM received over \$2.2 million in funding since 2009 from opioid manufacturers.
 5 AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of
 6 other funding) to participate. The benefits included allowing members to present educational
 7 programs at off-site dinner symposia in connection with AAPM’s marquee event – its annual
 8 meeting held in Palm Springs, California, or other resort locations.

10 420. AAPM describes the annual event as an “exclusive venue” for offering CMEs to
 11 doctors. Membership in the corporate relations council also allows drug company executives and
 12 marketing staff to meet with AAPM executive committee members in small settings. Defendants
 13 Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to
 14 doctors who attended this annual event. The conferences sponsored by AAPM heavily emphasized
 15 CME sessions on opioids – 37 out of roughly 40 at one conference alone.

17 421. AAPM’s staff understood that they and their industry funders were engaged in a
 18 common task. Defendants were able to influence AAPM through both their significant and regular
 19 funding and the leadership of pro-opioid KOLs within the organization.

20 422. AAPM and APS issued their own guidelines in 2009 (“2009 Guidelines”). AAPM,
 21 with the assistance, prompting, involvement, and funding of Defendants, issued the treatment
 22 guidelines discussed herein, and continued to recommend the use of opioids to treat chronic pain.
 23 Fourteen of the twenty-one panel members who drafted the 2009 Guidelines, including KOL
 24 Dr. Fine, received support from defendants Janssen, Cephalon, Endo, and Purdue. Of these
 25

26
 27 ¹⁵⁰ Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain
 28 Med., Chief of the Div. of Pain Med., Univ. of Cal., Davis (2005),
<http://www.medscape.org/viewarticle/500829>.

1 individuals, six received support from Purdue, eight from Teva, nine from Janssen, and nine from
2 Endo.

3 423. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State
4 University and founder of the Michigan Headache & Neurological Institute, resigned from the panel
5 because of his concerns that the 2009 Guidelines were influenced by contributions that drug
6 companies, including Purdue, Endo, Janssen, and Teva, made to the sponsoring organizations and
7 committee members.
8

9 424. Dr. Gilbert Fanciullo, now retired as a professor at Dartmouth College's Geisel
10 School of Medicine, who also served on the AAPM/APS guidelines panel, has since described them
11 as "skewed" by drug companies and "biased in many important respects," including the high
12 presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a
13 low risk of addiction.
14

15 425. The 2009 Guidelines have been a particularly effective channel of deception. They
16 have influenced not only treating physicians, but also the scientific literature on opioids; they were
17 reprinted in the *Journal of Pain*, have been cited hundreds of times in academic literature, were
18 disseminated during the relevant period, and were and are available online. Treatment guidelines are
19 especially influential with primary care physicians and family doctors to whom the Marketing
20 Defendants promoted opioids, whose lack of specialized training in pain management and opioids
21 makes them more reliant on, and less able to evaluate, these guidelines. For that reason, the CDC
22 has recognized that treatment guidelines can "change prescribing practices."¹⁵¹
23

24 426. The 2009 Guidelines are relied upon by doctors, especially general practitioners and
25 family doctors who have no specific training in treating chronic pain.
26

27 ¹⁵¹ Deborah Dowell, M.D., *et al.*, *CDC Guideline for Prescribing Opioids for Chronic Pain –*
28 *United States 2016*, 65(1) Morbidity & Mortality Wkly. Rep. 1, 2 (Mar. 18, 2016).

428. The Federation of State Medical Boards (“FSMB”) is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians.

430. Since 1998, the FSMB has been developing treatment guidelines for the use of opioids for the treatment of pain. The 1998 version, *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* (“1998 Guidelines”), was produced “in collaboration with pharmaceutical companies.” The 1998 Guidelines taught that the pharmaceutical companies helped author not that opioids could be appropriate in only limited cases after other treatments had failed, but that opioids were “essential” for treatment of chronic pain, including as a first prescription option.

431. A 2004 iteration of the 1998 Guidelines and the 2007 book, *Responsible Opioid Prescribing*, also made the same claims as the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach physicians nationwide, including in San Francisco.

433. The Marketing Defendants relied on the 1998 Guidelines to convey the alarming message that “under-treatment of pain” would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors’ fear of discipline on its head: doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught instead that they would be punished if they failed to prescribe opioids to their patients with chronic pain.

434. Founded in 2006, the Alliance for Patient Access (“APA”) is a self-described patient advocacy and health professional organization that styles itself as “a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care.”¹⁵² It is run

¹⁵² *About AfPA*, The All. for Patient Access, <https://local.bakersfield.com/washington-dc/community/non-profit-organizations/alliance-for-patient-access-202-224-2043> (last visited Mar. 12, 2020). References herein to APA include two affiliated groups: the Global Alliance for Patient Access and the Institute for Patient Access.

1 by Woodberry Associates LLC, a lobbying firm that was also established in 2006.¹⁵³ As of June
 2 2017, the APA listed 30 “Associate Members and Financial Supporters.” The list includes J&J,
 3 Endo, Mallinckrodt, Purdue and Cephalon.

4 435. APA board members have also directly received substantial funding from
 5 pharmaceutical companies.¹⁵⁴ For instance, board vice president Dr. Srinivas Nalamachu
 6 (“Nalamachu”), who practices in Kansas, received more than \$800,000 from 2013 through 2015
 7 from pharmaceutical companies – nearly all of it from manufacturers of opioids or drugs that treat
 8 opioids’ side effects, including from defendants Endo, Insys, Purdue and Cephalon. Nalamachu’s
 9 clinic was raided by FBI agents in connection with an investigation of Insys and its payment of
 10 kickbacks to physicians who prescribed Subsys. Other board members include Dr. Robert A.
 11 Yapundich from North Carolina, who received \$215,000 from 2013 through 2015 from
 12 pharmaceutical companies, including payments by defendants Cephalon and Mallinckrodt; Dr. Jack
 13 D. Schim from California, who received more than \$240,000 between 2013 and 2015 from
 14 pharmaceutical companies, including defendants Endo, Mallinckrodt and Cephalon; Dr. Howard
 15 Hoffberg from Maryland, who received \$153,000 between 2013 and 2015 from pharmaceutical
 16 companies, including defendants Endo, Purdue, Insys, Mallinckrodt and Cephalon; and Dr. Robin K.
 17 Dore from California, who received \$700,000 between 2013 and 2015 from pharmaceutical
 18 companies.
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25 ¹⁵³ Mary Chris Jaklevic, *Non-Profit Alliance for Patient Access Uses Journalists and Politicians to*
 26 *Push Big Pharma’s Agenda*, Health News Rev. (Oct. 2, 2017),
<https://www.healthnewsreview.org/2017/10/non-profit-alliance-patient-access-uses-journalists-politicians-push-big-pharmas-agenda/>.

27 ¹⁵⁴ All information concerning pharmaceutical company payments to doctors in this paragraph is
 28 from ProPublica’s Dollars for Docs database, <https://projects.propublica.org/docdollars/>.

* * *

We cannot merely assume that these programs will reduce prescription pain medication use and abuse.¹⁵⁶

Although well intentioned, many of the policies designed to address this problem have made it difficult for legitimate pain management centers to operate. For instance, in some states, [pain management centers] must be owned by physicians or professional corporations, must have a Board certified medical director, may need to pay for annual inspections, and are subject to increased record keeping and reporting requirements. . . . [I]t is not even certain that the regulations are helping prevent abuses.¹⁵⁷

¹⁵⁷ *Id.* at 5-6.

1 438. In addition, in an echo of earlier industry efforts to push back against what they
 2 termed “opiophobia,” the white paper laments the stigma associated with prescribing and taking pain
 3 medication:

4 Both pain patients and physicians can face negative perceptions and outright stigma.
 5 When patients with chronic pain can’t get their prescriptions for pain medication
 6 filled at a pharmacy, they may feel like they are doing something wrong – or even
 7 criminal. . . . Physicians can face similar stigma from peers. Physicians in non-pain
 8 specialty areas often look down on those who specialize in pain management – a
 9 situation fueled by the numerous regulations and fines that surround prescription pain
 10 medications.¹⁵⁸

11 439. In conclusion, the white paper states that “[p]rescription pain medications, and
 12 specifically the opioids, can provide substantial relief for people who are recovering from surgery,
 13 afflicted by chronic painful diseases, or experiencing pain associated with other conditions that does
 14 not adequately respond to over-the-counter drugs.”¹⁵⁹

15 440. The APA also issues “Patient Access Champion” financial awards to members of
 16 Congress, including 50 such awards in 2015. The awards were funded by a \$7.8 million donation
 17 from unnamed donors. While the awards are ostensibly given for protecting patients’ access to
 18 Medicare, and are thus touted by their recipients as demonstrating a commitment to protecting the
 19 rights of senior citizens and the middle class, they appear to be given to provide cover to and reward
 20 members of Congress who have supported the APA’s agenda.

21 441. The APA also lobbies Congress directly. In 2015, the APA signed onto a letter
 22 supporting legislation proposed to limit the ability of the DEA to police pill mills by enforcing the
 23 “suspicious orders” provision of the Controlled Substances Act. The AAPM is also a signatory to
 24 this letter. An internal DOJ memo stated that the proposed bill ““could actually result in increased
 25

26 ¹⁵⁸ *Id.* at 6.

27 ¹⁵⁹ *Id.* at 7.

diversion, abuse, and public health and safety consequences”¹⁶⁰ and, according to DEA chief administrative law judge John J. Mulrooney (“Mulrooney”), the law would make it “all but logically impossible” to prosecute manufacturers and distributors, like the Defendants here, in the federal courts.¹⁶¹ The bill passed both houses of Congress and was signed into law in 2016.

(5) U.S. Pain Foundation

442. The U.S. Pain Foundation (“USPF”) was another Front Group with systematic connections and interpersonal relationships with the Marketing Defendants. The USPF was one of the largest recipients of contributions from the Marketing Defendants, collecting nearly \$3 million in payments between 2012 and 2015 alone. The USPF was also a critical component of the Marketing Defendants’ lobbying efforts to reduce the limits on over-prescription. The USPF advertises its ties to the Marketing Defendants, listing opioid manufacturers like Pfizer, Teva, Depomed, Endo, Purdue, McNeil (*i.e.*, Janssen), and Mallinckrodt as “Platinum,” “Gold,” and “Basic” corporate members.¹⁶² Industry Front Groups like the AAPM, APS, and PhRMA are also members of varying levels in the USPF.

(6) American Geriatrics Society

443. The American Geriatrics Society (“AGS”) was another Front Group with systematic connections and interpersonal relationships with the Marketing Defendants. AGS was a large recipient of contributions from the Marketing Defendants, including Endo, Purdue and Janssen. AGS contracted with Purdue, Endo and Janssen to disseminate guidelines regarding the use of

¹⁶⁰ Bill Whitaker, *Ex-DEA Agent: Opioid Crisis Fueled by Drug Industry and Congress*, CBS News (Oct. 17, 2017), <https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress/>.

¹⁶¹ John J. Mulrooney, II & Katherine E. Legel, *Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters*, 101 Marquette L. Rev. 333, 346 (2017).

¹⁶² U.S. S. Homeland Sec. & Governmental Aff. Comm., Ranking Members’ Office, *Fueling an Epidemic* at 12 (Feb. 12, 2018), <https://www.hsdl.org/?abstract&did=808171>; *see also* Funding, U.S. Pain Found., <https://uspainfoundation.org/funding/> (last visited Mar. 12, 2020).

1 opioids for chronic pain in 2002 (*The Management of Persistent Pain in Older Persons*, hereinafter
 2 “2002 AGS Guidelines”) and 2009 (*Pharmacological Management of Persistent Pain in Older*
 3 *Persons*,¹⁶³ hereinafter “2009 AGS Guidelines”). According to news reports, AGS has received at
 4 least \$344,000 in funding from opioid manufacturers since 2009.¹⁶⁴ AGS’s complicity in the
 5 common purpose with the Marketing Defendants is evidenced by the fact that AGS internal
 6 discussions in August 2009 reveal that it did not want to receive up-front funding from drug
 7 companies, which would suggest drug company influence, but would instead accept commercial
 8 support to disseminate pro-opioid publications.

10 444. The 2009 AGS Guidelines recommended that “[a]ll patients with moderate to severe
 11 pain . . . should be considered for opioid therapy.” The panel made “strong recommendations” in
 12 this regard despite “low quality of evidence” and concluded that the risk of addiction is manageable
 13 for patients, even with a prior history of drug abuse.¹⁶⁵ The 2009 AGS Guidelines further
 14 recommended that “the risks [of addiction] are exceedingly low in older patients with no current or
 15 past history of substance abuse.” These recommendations are not supported by any study or other
 16 reliable scientific evidence. Nevertheless, they have been cited over 1,833 times in Google Scholar
 17 (which allows users to search scholarly publications that would have been relied on by researchers
 18 and prescribers) since their 2009 publication and as recently as this year.

20 445. Representatives of the Marketing Defendants, often at informal meetings at
 21 conferences, suggested activities, lobbying efforts, and publications for AGS to pursue. AGS then
 22

24 ¹⁶³ *Pharmacological Mgmt. of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc’y 1331,
 25 1339, 1342 (2009), <https://academic.oup.com/painmedicine/article/10/6/1062/1843022>.

26 ¹⁶⁴ John Fauber & Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, Milwaukee J.
 27 Sentinel (May 30, 2012) <https://www.medpagetoday.com/geriatrics/painmanagement/32967>.

28 ¹⁶⁵ *Pharmacological Mgmt. of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc’y 1331,
 1342 (2009), <https://academic.oup.com/painmedicine/article/10/6/1062/1843022>.

1 submitted grant proposals seeking to fund these activities and publications, knowing that drug
2 companies would support projects conceived as a result of these communications.

3 446. Members of AGS's board of directors were doctors who were on the Marketing
4 Defendants' payrolls, either as consultants or speakers at medical events. As described below, many
5 of the KOLs also served in leadership positions within the AGS.
6

7 **b. The Marketing Defendants Paid KOLs to Deceptively**
8 **Promote Opioid Use**

9 447. To falsely promote their opioids, the Marketing Defendants paid and cultivated a
10 select circle of doctors who were chosen and sponsored by the Marketing Defendants for their
11 supportive messages. As set forth below, pro-opioid doctors have been at the hub of the Marketing
12 Defendants' well-funded, pervasive marketing scheme since its inception and were used to create the
13 grave misperception that science and legitimate medical professionals favored the wider and broader
14 use of opioids. These doctors include Dr. Russell Portenoy ("Dr. Portenoy") and Dr. Webster, as set
15 forth in this section, as well as Dr. Fine and Dr. Fishman, as set forth below.

16 448. Although these KOLs were funded by the Marketing Defendants, the KOLs were
17 used extensively to present the appearance that unbiased and reliable medical research supporting the
18 broad use of opioid therapy for chronic pain had been conducted and was being reported on by
19 independent medical professionals.
20

21 449. As the Marketing Defendants' false marketing scheme picked up steam, these pro-
22 opioid KOLs wrote, consulted on, edited, and lent their names to books and articles and gave
23 speeches and CMEs supportive of opioid therapy for chronic pain. They served on committees that
24 developed treatment guidelines that strongly encouraged the use of opioids to treat chronic pain and
25 they were placed on boards of pro-opioid advocacy groups and professional societies that develop,
26 select, and present CMEs.
27
28

1 450. Through use of their KOLs and strategic placement of these KOLs throughout every
2 critical distribution channel of information within the medical community, the Marketing Defendants
3 were able to exert control of each of these modalities through which doctors receive their
4 information.

5 451. In return for their pro-opioid advocacy, the Marketing Defendants' KOLs received
6 money, prestige, recognition, research funding, and avenues to publish. For example, Dr. Webster
7 has received funding from Endo, Purdue, and Cephalon. Dr. Fine has received funding from
8 Janssen, Cephalon, Endo, and Purdue.

9 452. The Marketing Defendants carefully vetted their KOLs to ensure that they were likely
10 to remain on-message and supportive of the Marketing Defendants' agenda. The Marketing
11 Defendants also kept close tabs on the content of the materials published by these KOLs. And, of
12 course, the Marketing Defendants kept these KOLs well funded to enable them to push the
13 Marketing Defendants' deceptive message out to the medical community.

14 453. Once the Marketing Defendants identified and funded KOLs and those KOLs began
15 to publish "scientific" papers supporting the Marketing Defendants' false position that opioids were
16 safe and effective for treatment of chronic pain, the Marketing Defendants poured significant funds
17 and resources into a marketing machine that widely cited and promoted their KOLs and studies or
18 articles by their KOLs to drive prescription of opioids for chronic pain. The Marketing Defendants
19 cited to, distributed, and marketed these studies and articles by their KOLs as if they were
20 independent medical literature so that it would be well received by the medical community. By
21 contrast, the Marketing Defendants did not support, acknowledge, or disseminate the truly
22 independent publications of doctors critical of the use of chronic opioid therapy.

23 454. In their promotion of the use of opioids to treat chronic pain, the Marketing
24 Defendants' KOLs knew that their statements were false and misleading, or they recklessly
25

disregarded the truth in doing so, but they continued to publish their misstatements to benefit themselves and the Marketing Defendants.

(1) Dr. Russell Portenoy

455. In 1986, Dr. Russell Portenoy, who later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York while at the same time serving as a top spokesperson for drug companies, published an article reporting that “[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy.”¹⁶⁶

456. Writing in 1994, Dr. Portenoy described the prevailing attitudes regarding the dangers of long-term use of opioids:

The traditional approach to chronic non-malignant pain does not accept the long-term administration of opioid drugs. This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. ***Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.***¹⁶⁷

According to Dr. Portenoy, the foregoing problems could constitute “compelling reasons to reject long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain.”¹⁶⁸

¹⁶⁶ R. Portenoy & K. Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases*, 25(2) Pain 171 (1986), <https://www.ncbi.nlm.nih.gov/pubmed/2873550>.

¹⁶⁷ Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields & J.C. Liebeskind eds., 1994).

¹⁶⁸ *Id.*

1 457. Despite having taken this position on long-term opioid treatment, Dr. Portenoy ended
 2 up becoming a spokesperson for Purdue and other Marketing Defendants, promoting the use of
 3 prescription opioids and minimizing their risks. A respected leader in the field of pain treatment,
 4 Dr. Portenoy was highly influential. Dr. Andrew Kolodny, cofounder of *Physicians for Responsible*
 5 *Opioid Prescribing*, described him ““lecturing around the country as a religious-like figure. . . . The
 6 megaphone for Portenoy is Purdue, which flies in people to resorts to hear him speak. It was a
 7 compelling message: “Docs have been letting patients suffer; nobody really gets addicted; it’s been
 8 studied.””¹⁶⁹

10 458. As one organizer of CME seminars who worked with Dr. Portenoy and Purdue
 11 pointed out, “had Portenoy not had Purdue’s money behind him, he would have published some
 12 papers, made some speeches, and his influence would have been minor. With Purdue’s millions
 13 behind him, his message, which dovetailed with their marketing plans, was hugely magnified.”¹⁷⁰

15 459. Dr. Portenoy was also a critical component of the Marketing Defendants’ control over
 16 their Front Groups. Specifically, Dr. Portenoy sat as a director on the board of APF. He was also
 17 the president of APS.

18 460. In recent years, some of the Marketing Defendants’ KOLs have conceded that many
 19 of their past claims in support of opioid use lacked evidence or support in the scientific literature.¹⁷¹

20 Dr. Portenoy has now admitted that he minimized the risks of opioids and that he “gave innumerable
 21

24 ¹⁶⁹ Sam Quiñones, *Dreamland: The True Tale of America’s Opiate Epidemic*, at 314 (Bloomsbury Press 2015).

25 ¹⁷⁰ *Id.* at 136.

26 ¹⁷¹ See, e.g., John Fauber, *Painkiller Boom Fueled by Networking*, J. Sentinel (Feb. 18, 2012),
 27 <http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html/> (reporting that a key Endo KOL acknowledged that opioid marketing went too far).
 28

1 lectures in the late 1980s and '90s about addiction that weren't true."¹⁷² He mused, "Did I teach
 2 about pain management, specifically about opioid therapy, in a way that reflects misinformation?
 3 Well, against the standards of 2012, I guess I did" ¹⁷³

4 461. In a 2011 interview released by Physicians for Responsible Opioid Prescribing, Dr.
 5 Portenoy stated that his earlier work purposefully relied on evidence that was not "real" and left real
 6 evidence behind:

8 I gave so many lectures to primary care audiences in which the Porter and Jick article
 9 was just one piece of data that I would then cite, and I would cite six, seven, maybe
 10 ten different avenues of thought or avenues of evidence, ***none of which represented***
 11 ***real evidence***, and yet what I was trying to do was to create a narrative so that the
 12 primary care audience would look at this information ***in toto*** and feel more
 13 comfortable about opioids in a way they hadn't before. ***In essence this was***
 14 ***education to destigmatize [opioids], and because the primary goal was to***
 15 ***destigmatize, we often left evidence behind.***¹⁷⁴

16 462. Several years earlier, when interviewed by journalist Barry Meier for his 2003 book,
 17 *Pain Killer*, Dr. Portenoy was more direct: "It was pseudoscience. . . . I guess I'm going to have
 18 always to live with that one."¹⁷⁵

19 (2) Dr. Lynn Webster

20 463. Another KOL, Dr. Lynn Webster, was the co-founder and chief medical director of
 21 the Lifetree Clinical Research & Pain Clinic in Salt Lake City, Utah. Dr. Webster was president in
 22 2013 and is a current board member of AAPM, a Front Group that ardently supports chronic opioid
 23 therapy. He is a Senior Editor of *Pain Medicine*, the same journal that published Endo's special

24 ¹⁷² Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall St. J. (Dec. 17, 2012), <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>.

25 ¹⁷³ *Id.*

26 ¹⁷⁴ Harrison Jacobs, *This 1-Paragraph Letter May Have Launched the Opioid Epidemic*, AOL (May 26, 2016, 1:39 PM), <https://www.aol.com/article/2016/05/26/letter-may-have-launched-opioid-epidemic/21384408/>. Andrew Kolodny, *Opioids for Chronic Pain: Addiction is NOT Rare*, YouTube (Oct. 30, 2011), <https://www.youtube.com/watch?v=DgyuBWN9D4w&feature=youtu.be>.

27 ¹⁷⁵ Barry Meier, *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death* 277 (Rodale 2003).

1 advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs
2 sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant
3 funding from Defendants (including nearly \$2 million from Cephalon).

4 464. Dr. Webster created and promoted the Opioid Risk Tool (“ORT”), a five question,
5 one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage
6 the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort
7 patients likely to become addicted is an important tool in giving doctors confidence to prescribe
8 opioids long term, and for this reason, references to screening appear in various industry-supported
9 guidelines. Versions of Dr. Webster’s ORT appear on, or are linked to, websites run by Endo,
10 Janssen, and Purdue. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue
11 titled *Managing Patient’s Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended
12 use of risk screening tools, urine testing, and patient agreements to prevent “overuse of
13 prescriptions” and “overdose deaths.” This webinar was available to and was intended to reach
14 doctors across the United States, including in San Francisco.

15 465. Dr. Webster was himself tied to numerous overdose deaths. He and the Lifetree
16 Clinic were investigated by the DEA for overprescribing opioids after 20 patients died from
17 overdoses. In keeping with the Marketing Defendants’ promotional messages, Dr. Webster
18 apparently believed the solution to patients’ tolerance or addictive behaviors was more opioids: he
19 prescribed staggering quantities of pills.

20 466. At an AAPM annual meeting held February 22 through 25, 2006, Cephalon
21 sponsored a presentation by Dr. Webster and others titled *Open-label study of fentanyl effervescent*
22 *buccal tablets in patients with chronic pain and breakthrough pain: Interim safety results*. The
23 presentation’s agenda description states: “Most patients with chronic pain experience episodes of
24 breakthrough pain, yet no currently available pharmacologic agent is ideal for its treatment.” The
25
26
27
28

1 presentation purports to cover a study analyzing the safety of a new form of fentanyl buccal tablets
 2 in the chronic pain setting and promises to show that the “[i]nterim results of this study suggest that
 3 FEBT is safe and well-tolerated in patients with chronic pain and BTP.” This CME effectively
 4 amounted to off-label promotion of Cephalon’s opioids – the only drugs in this category – for
 5 chronic pain, even though they were approved only for cancer pain.
 6

7 467. Cephalon sponsored a CME written by Dr. Webster, *Optimizing Opioid Treatment for*
 8 *Breakthrough Pain*, offered by Medscape, LLC from September 28, 2007 through December 15,
 9 2008. The CME taught that non-opioid analgesics and combination opioids containing non-opioids
 10 such as aspirin and acetaminophen are less effective at treating breakthrough pain because of dose
 11 limitations on the non-opioid component.
 12

13 (3) Dr. Perry Fine

14 468. Dr. Perry Fine’s ties to the Marketing Defendants are well documented. He has
 15 authored articles and testified in court cases and before state and federal committees, and he, too, has
 16 argued against legislation restricting high-dose opioid prescriptions for non-cancer patients. He has
 17 served on Purdue’s advisory board, provided medical legal consulting for Janssen, and participated
 18 in CME activities for Endo, along with serving in these capacities for several other drug companies.
 19 He co-chaired the APS/AAPM Opioid Guideline Panel, served as treasurer of the AAPM from 2007
 20 to 2010 and as president of that group from 2011 to 2013, and was on the board of directors of APF.
 21

22 469. Multiple videos feature Dr. Fine delivering educational talks about prescription
 23 opioids. He even testified at trial that the 1,500 pills a month prescribed to celebrity Anna Nicole
 24 Smith for pain did not make her an addict before her death.

25 470. He has also acknowledged having failed to disclose numerous conflicts of interest.
 26 For example, Dr. Fine failed to fully disclose payments received as required by his employer, the
 27 University of Utah – telling the university that he had received under \$5,000 in 2010 from J&J for
 28

1 providing “educational” services, but J&J’s website states that the company paid him \$32,017 for
 2 consulting, promotional talks, meals and travel that year.

3 471. Dr. Fine and Dr. Portenoy co-wrote *A Clinical Guide to Opioid Analgesia*, in which
 4 they downplayed the risks of opioid treatment, such as respiratory depression and addiction:

5 At clinically appropriate doses, . . . respiratory rate typically does not decline.
 6 Tolerance to the respiratory effects usually develops quickly, and doses can be
 7 steadily increased without risk.

8 Overall, the literature provides evidence that the outcomes of drug abuse and
 9 addiction are rare among patients who receive opioids for a short period (*i.e.*, for
 10 acute pain) and among those with no history of abuse who receive long-term therapy
 11 for medical indications.¹⁷⁶

12 472. In November 2010, Dr. Fine and others published an article presenting the results of
 13 another Cephalon-sponsored study titled *Long-Term Safety and Tolerability of Fentanyl Buccal*
 14 *Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An*
 15 *18-Month Study*.¹⁷⁷ In that article, Dr. Fine explained that the 18-month “open-label” study
 16 “assessed the safety and tolerability of FBT [Fentora] for the [long-term] treatment of BTP in a large
 17 cohort . . . of opioid-tolerant patients receiving around-the-clock . . . opioids for . . . noncancer pain.”
 18 The article acknowledged that: (a) “[t]here has been a steady increase in the use of opioids for the
 19 management of chronic noncancer pain over the past two decades”; (b) the “widespread acceptance”
 20 had led to the publishing of practice guidelines “to provide evidence- and consensus-based
 21 recommendations for the optimal use of opioids in the management of chronic pain”; and (c) those
 22 guidelines lacked “data assessing the long-term benefits and harms of opioid therapy for chronic
 23 pain.”¹⁷⁸

24 ¹⁷⁶ Perry G. Fine, MD & Russell K. Portenoy, MD, *A Clinical Guide to Opioid Analgesia*, McGraw-
 25 Hill Companies, 2004, at 20, 26, 34, 40, <http://www.thblack.com/links/RSD/OpioidHandbook.pdf>.

26 ¹⁷⁷ Perry G. Fine, *et al.*, *Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the*
 27 *Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month*
Study, 40(5) J. Pain & Symptom Mgmt. 747-60 (Nov. 2010).

28 ¹⁷⁸ *Id.* at 747-48.

473. The article concluded: “[T]he safety and tolerability profile of FBT in this study was generally typical of a potent opioid. The [adverse events] observed were, in most cases, predictable, manageable, and tolerable.” It also concluded that the number of abuse-related events was “small.”¹⁷⁹

474. Multiple videos feature Dr. Fine delivering educational talks about the drugs. In one video from 2011, titled *Optimizing Opioid Therapy*, he sets forth a “Guideline for Chronic Opioid Therapy” discussing “opioid rotation” (switching from one opioid to another) not only for cancer patients, but for non-cancer patients, and suggests it may take four or five switches over a person’s “lifetime” to manage pain.¹⁸⁰ He states the “goal is to improve effectiveness which is different from efficacy and safety.” Rather, for chronic pain patients, effectiveness “is a balance of therapeutic good and adverse events *over the course of years*.” The entire program assumes that opioids are an appropriate treatment over a “protracted periods of time” and even over a patient’s entire “lifetime.” He even suggests that opioids can be used to treat *sleep apnea*. He further states that the associated risks of addiction and abuse can be managed by doctors and evaluated with “tools,” but leaves that for “a whole other lecture.”¹⁸¹

(4) Dr. Scott Fishman

475. Dr. Scott Fishman is a physician whose ties to the opioid drug industry are legion. He has served as an APF board member and as president of the AAPM, and has participated yearly in numerous CME activities for which he received “market rate honoraria.” As discussed below, he has authored publications, including the seminal guides on opioid prescribing, which were funded by the Marketing Defendants. He has also worked to oppose legislation requiring doctors and others to

¹⁷⁹ *Id.* at 759.

¹⁸⁰ Perry A. Fine, *Safe and Effective Opioid Rotation*, YouTube (Nov. 8, 2012), <https://www.youtube.com/watch?v=G3II9yqgXI>.

181 *Id.*

1 consult pain specialists before prescribing high doses of opioids to non-cancer patients. He has
 2 himself acknowledged his failure to disclose all potential conflicts of interest in a letter in the
 3 *Journal of the American Medical Association* titled “Incomplete Financial Disclosures in a Letter on
 4 Reducing Opioid Abuse and Diversion.”¹⁸²

5
 6 476. In 2007, Dr. Fishman authored a physician’s guide on the use of opioids to treat
 7 chronic pain titled *Responsible Opioid Prescribing*, which promoted the notion that long-term opioid
 8 treatment was a viable and safe option for treating chronic pain.

9 477. In 2012, Dr. Fishman updated the guide, continuing to emphasize the “catastrophic”
 10 “under-treatment” of pain and the “crisis” such under-treatment created:

11 Given the magnitude of the problems related to opioid analgesics, it can be tempting
 12 to resort to draconian solutions: clinicians may simply stop prescribing opioids, or
 13 legislation intended to improve pharmacovigilance may inadvertently curtail patient
 14 access to care. As we work to reduce diversion and misuse of prescription opioids,
 it’s critical to remember that the problem of unrelieved pain remains as urgent as
 ever.¹⁸³

15 478. The updated guide still contains assurances that “[o]pioid therapy to relieve pain and
 16 improve function is a legitimate medical practice for acute and chronic pain of both cancer and
 17 noncancer origins.”¹⁸⁴

18 479. In another guide by Dr. Fishman, he continues to downplay the risk of addiction: “I
 19 believe clinicians must be very careful with the label ‘addict.’ I draw a distinction between a
 20
 21
 22

23 ¹⁸² Scott M. Fishman, Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and
 24 Diversion, 306 (13) JAMA 1445 (Oct. 5, 2011), <https://jamanetwork.com/journals/jama/article-abstract/1104464?redirect=true>; Tracy Weber & Charles Ornstein, *Two Leaders in Pain Treatment*
 25 *Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011, 9:14 AM),
<https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry>.

26 ¹⁸³ Scott M. Fishman, *Responsible Opioid Prescribing: A Guide for Michigan Clinicians* 10-11
 27 (Waterford Life Sciences, 2d ed. 2012).

28 ¹⁸⁴ *Id.*

1 ‘chemical coper’ and an addict.”¹⁸⁵ The guide also continues to present symptoms of addiction as
 2 symptoms of “pseudoaddiction.”

3 **c. The Marketing Defendants Disseminated Their**
 4 **Misrepresentations Through CME Programs**

5 480. Now that the Marketing Defendants had both a group of physician promoters and had
 6 built a false body of “literature,” Defendants needed to make sure their false marketing message was
 7 widely distributed.

8 481. One way the Marketing Defendants aggressively distributed their false message was
 9 through thousands of CME courses.

10 482. A CME is a professional education program provided to doctors. Doctors are
 11 required to attend a certain number and, often, type of CME programs each year as a condition of
 12 their licensure. These programs are delivered in person, often in connection with professional
 13 organizations’ conferences, and online, or through written publications. Doctors rely on CMEs not
 14 only to satisfy licensing requirements, but also to get information on new developments in medicine
 15 or to deepen their knowledge in specific areas of practice. Because CMEs typically are taught by
 16 KOLs who are highly respected in their fields, and are thought to reflect these physicians’ medical
 17 expertise, they can be especially influential with doctors.
 18

19 483. The countless doctors and other health care professionals who participate in
 20 accredited CMEs constitute an enormously important audience for opioid reeducation. As one
 21 target, Defendants aimed to reach general practitioners, whose broad area of practice and lack of
 22 expertise and specialized training in pain management made them particularly dependent upon
 23 CMEs and, as a result, especially susceptible to the Marketing Defendants’ deceptions.
 24

25
 26
 27 ¹⁸⁵ Scott M. Fishman, *Listening to Pain: A Physician’s Guide to Improving Pain Management*
 28 *Through Better Communication* 45 (Oxford University Press 2012).

1 484. The Marketing Defendants sponsored CMEs that were delivered thousands of times,
 2 promoting chronic opioid therapy and supporting and disseminating the deceptive and biased
 3 messages described in this complaint. These CMEs, while often generically titled to relate to the
 4 treatment of chronic pain, focus on opioids to the exclusion of alternative treatments, inflate the
 5 benefits of opioids, and frequently omit or downplay their risks and adverse effects.

6 485. Cephalon sponsored numerous CME programs, which were made widely available
 7 through organizations like Medscape, LLC (“Medscape”), and which disseminated false and
 8 misleading information to physicians across the country.

9 486. Another Cephalon-sponsored CME presentation titled *Breakthrough Pain: Treatment*
 10 *Rationale with Opioids* was available on Medscape starting September 16, 2003 and was given by a
 11 self-professed pain management doctor who treated “previously operated back, complex pain
 12 syndromes, the neuropathies, and interstitial cystitis.” He describes the pain process as a non-time-
 13 dependent continuum that requires a balanced analgesia approach using “targeted
 14 pharmacotherapeutics to affect multiple points in the pain-signaling pathway.”¹⁸⁶ The doctor lists
 15 fentanyl as one of the most effective opioids available for treating breakthrough pain, describing its
 16 use as an expected and normal part of the pain management process. Nowhere in the CME is cancer
 17 or cancer-related pain even mentioned, despite FDA restrictions that fentanyl use be limited to
 18 cancer-related pain.

19 487. Teva paid to have a CME it sponsored, *Opioid-Based Management of Persistent and*
 20 *Breakthrough Pain*, published in a supplement of *Pain Medicine News* in 2009. The CME instructed
 21 doctors that “clinically, broad classification of pain syndromes as either cancer- or noncancer-related
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27 ¹⁸⁶ Daniel S. Bennett, *Breakthrough Pain: Treatment Rationale with Opioids*, Medscape (Sept. 16,
 28 2003), <http://www.medscape.org/viewarticle/461612>.

1 has limited utility” and recommended Actiq and Fentora for patients with chronic pain. The CME is
2 still available online.

3 488. *Responsible Opioid Prescribing* was sponsored by Purdue, Endo and Teva. The
4 FSMB website described it as the “leading continuing medical education (CME) activity for
5 prescribers of opioid medications.” Endo sales representatives distributed copies of *Responsible*
6 *Opioid Prescribing* with a special introductory letter from Dr. Fishman.

7
8 489. In all, more than 163,000 copies of *Responsible Opioid Prescribing* were distributed
9 nationally.

10 490. The American Medical Association (“AMA”) has recognized the impropriety that
11 pharmaceutical company-funded CMEs creates, stating that support from drug companies with a
12 financial interest in the content being promoted “creates conditions in which external interests could
13 influence the availability and/or content” of the programs and urges that “[w]hen possible, CME[s]
14 should be provided without such support or the participation of individuals who have financial
15 interests in the educational subject matter.”¹⁸⁷

16
17 491. Physicians attended or reviewed CMEs sponsored by the Marketing Defendants
18 during the relevant time period and were misled by them.

19 492. By sponsoring CME programs put on by Front Groups like APF, AAPM, and others,
20 the Marketing Defendants could expect instructors to deliver messages favorable to them, as these
21 organizations were dependent on the Marketing Defendants for other projects. The sponsoring
22 organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic
23 opioid therapy. Marketing Defendant-driven content in these CMEs had a direct and immediate
24 effect on prescribers’ views on opioids. Producers of CMEs and the Marketing Defendants both
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26
27

28 ¹⁸⁷ Opinion 9.0115, *Financial Relationships with Industry in CME*, Am. Med. Ass’n 1 (Nov. 2011).

1 measured the effects of CMEs on prescribers' views on opioids and their absorption of specific
 2 messages, confirming the strategic marketing purpose in supporting them.

3 **d. The Marketing Defendants Used "Branded"**
 4 **Advertising to Promote Their Products to Doctors and**
 5 **Consumers**

6 493. The Marketing Defendants engaged in widespread advertising campaigns touting the
 7 benefits of their branded drugs. The Marketing Defendants published print advertisements in a
 8 broad array of medical journals, ranging from those aimed at specialists, such as the *Journal of Pain*
 9 and *Clinical Journal of Pain*, to journals with wider medical audiences, such as the *Journal of the*
 10 *American Medical Association*. The Marketing Defendants collectively spent more than \$14 million
 11 on the medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. The
 12 2011 total includes \$8.3 million by Purdue, \$4.9 million by Janssen, and \$1.1 million by Endo.

13 494. The Marketing Defendants also targeted consumers in their advertising. They knew
 14 that physicians are more likely to prescribe a drug if a patient specifically requests it.¹⁸⁸ They also
 15 knew that this willingness to acquiesce to such patient requests holds true even for opioids and for
 16 conditions for which they are not approved.¹⁸⁹ Endo's research, for example, also found that such
 17 communications resulted in greater patient "brand loyalty," with longer durations of Opana ER
 18 therapy and fewer discontinuations. The Marketing Defendants thus increasingly took their opioid
 19 sales campaigns directly to consumers, including through patient-focused "education and support"
 20 materials in the form of pamphlets, videos, or other publications that patients could view in their
 21 physician's office.
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 23
 24

25 ¹⁸⁸ In one study, for example, nearly 20% of sciatica patients requesting oxycodone received a
 26 prescription for it, compared with 1% of those making no specific request. J.B. McKinlay *et al.*,
 27 *Effects of Patient Medication Requests on Physician Prescribing Behavior*, 52(4) Med. Care 294-
 28 299 (Apr. 2014).

¹⁸⁹ *Id.*

e. **The Marketing Defendants Used “Unbranded” Advertising to Promote Opioid Use for Chronic Pain Without FDA Review**

495. The Marketing Defendants also aggressively promoted opioids through “unbranded advertising” to generally tout the benefits of opioids without specifically naming a particular brand-name opioid drug. Instead, unbranded advertising is usually framed as “disease awareness” – encouraging consumers to “talk to your doctor” about a certain health condition without promoting a specific product and, therefore, without providing balanced disclosures about the product’s limits and risks. In contrast, a pharmaceutical company’s “branded” advertisement that identifies a specific medication and its indication (*i.e.*, the condition which the drug is approved to treat) must also include possible side effects and contraindications – what the FDA Guidance on pharmaceutical advertising refers to as “fair balance.” Branded advertising is also subject to FDA review for consistency with the drug’s FDA-approved label. Through unbranded materials, the Marketing Defendants expanded the overall acceptance of and demand for chronic opioid therapy without the restrictions imposed by regulations on branded advertising.

496. Many of the Marketing Defendants utilized unbranded websites to promote opioid use without promoting a specific branded drug, such as Purdue’s pain-management website *www.InTheFaceOfPain.com*. The website contained testimonials from several dozen “advocates,” including health care providers, urging more pain treatment. The website presented the advocates as neutral and unbiased, but an investigation by the New York Attorney General later revealed that Purdue paid the advocates hundreds of thousands of dollars.

f. **The Marketing Defendants Funded, Edited, and Distributed Publications that Supported Their Misrepresentations**

497. The Marketing Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that: (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was likely

1 to shape the perceptions of prescribers, patients, and payors. This literature served marketing goals,
 2 rather than scientific standards, and was intended to persuade doctors and consumers that the
 3 benefits of long-term opioid use outweighed the risks.

4 498. To accomplish their goal, the Marketing Defendants – sometimes through third-party
 5 consultants and/or Front Groups – commissioned, edited, and arranged for the placement of
 6 favorable articles in academic journals.

7
 8 499. The Marketing Defendants' plans for these materials did not originate in the
 9 departments with the organizations that were responsible for research, development, or any other
 10 area that would have specialized knowledge about the drugs and their effects on patients; rather, they
 11 originated in the Marketing Defendants' marketing departments.

12 500. The Marketing Defendants made sure that favorable articles were disseminated and
 13 cited widely in the medical literature, even when the Marketing Defendants knew that the articles
 14 distorted the significance or meaning of the underlying study, as with the Porter & Jick Letter. The
 15 Marketing Defendants also frequently relied on unpublished data or posters, neither of which are
 16 subject to peer review, but were presented as valid scientific evidence.

17
 18 501. The Marketing Defendants published or commissioned deceptive review articles,
 19 letters to the editor, commentaries, case-study reports, and newsletters aimed at discrediting or
 20 suppressing negative information that contradicted their claims or raised concerns about chronic
 21 opioid therapy.

22
 23 502. For example, in 2007, Cephalon sponsored the publication of an article, titled *Impact*
 24 *of Breakthrough Pain on Quality of Life in Patients with Chronic, Noncancer Pain: Patient*
 25 *Perceptions and Effect of Treatment with Oral Transmucosal Fentanyl Citrate*,¹⁹⁰ published in the

26
 27 ¹⁹⁰ Donald R. Taylor, *et al.*, *Impact of Breakthrough Pain on Quality of Life in Patients With*
 28 *Chronic, Noncancer Pain: Patient Perceptions and Effect of Treatment With Oral Transmucosal*
Fentanyl Citrate (OTFC, ACTIQ), 8(3) Pain Med. 281-88 (Mar. 2007).

1 nationally circulated journal Pain Medicine, to support its effort to expand the use of its branded
 2 fentanyl products. The article’s authors (including Dr. Webster, discussed above) stated that the
 3 “OTFC [fentanyl] has been shown to relieve BTP more rapidly than conventional oral, normal-
 4 release, or ‘short acting’ opioids” and that “[t]he purpose of [the] study was to provide a qualitative
 5 evaluation of the effect of BTP on the [quality of life] of noncancer pain patients.” The number-one-
 6 diagnosed cause of chronic pain in the patients studied was back pain (44%), followed by
 7 musculoskeletal pain (12%), and head pain (7%). The article cites Dr. Portenoy and recommends
 8 fentanyl for non-cancer BTP patients:
 9

10 In summary, BTP appears to be a clinically important condition in patients
 11 with chronic noncancer pain and is associated with an adverse impact on QoL. This
 12 qualitative study on the negative impact of BTP and the potential benefits of BTP-
 specific therapy suggests several domains that may be helpful in developing BTP-
 specific, [quality of life] assessment tools.¹⁹¹

13 **g. The Marketing Defendants Used Detailing to Directly**
 14 **Disseminate Their Misrepresentations to Prescribers**

15 503. The Marketing Defendants’ sales representatives executed carefully crafted marketing
 16 tactics, developed at the highest rungs of their corporate ladders, to reach targeted doctors with
 17 centrally orchestrated messages. The Marketing Defendants’ sales representatives also distributed
 18 third-party marketing material to their target audience that was deceptive.

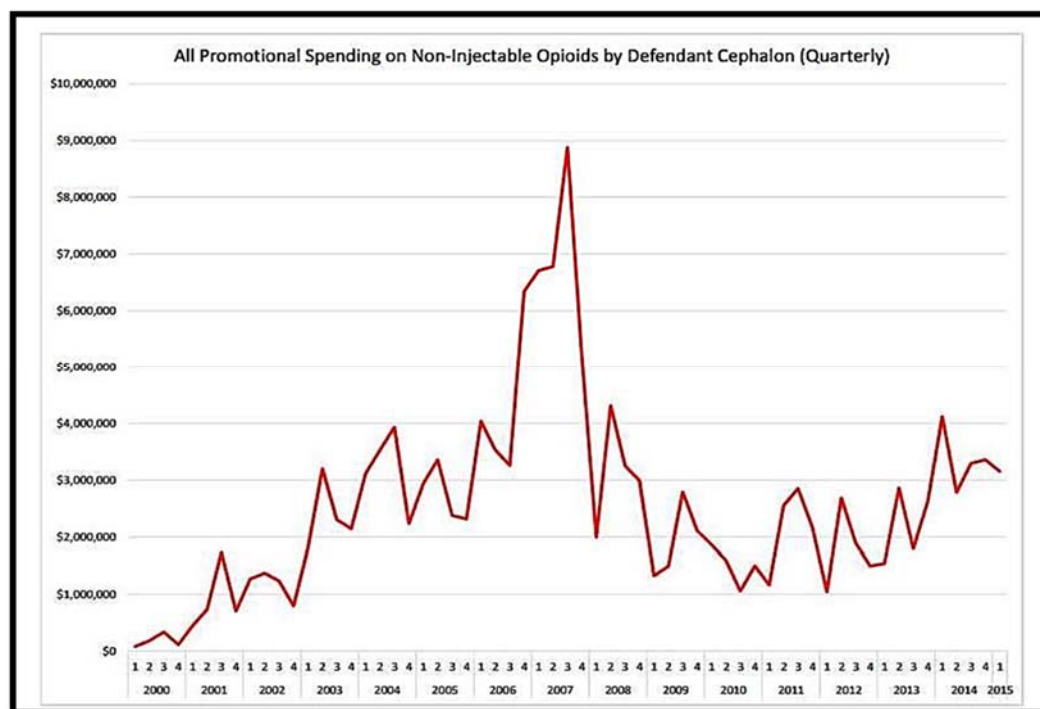
19 504. Each Marketing Defendant promoted opioids through sales representatives (also
 20 called “detailers”) and, upon information and belief, small group speaker programs to reach out to
 21 individual prescribers. By establishing close relationships with doctors, the Marketing Defendants
 22 were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them
 23 to promote their opioids and to allay individual prescribers’ concerns about prescribing opioids for
 24 chronic pain.
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28 ¹⁹¹ *Id.* at 287.

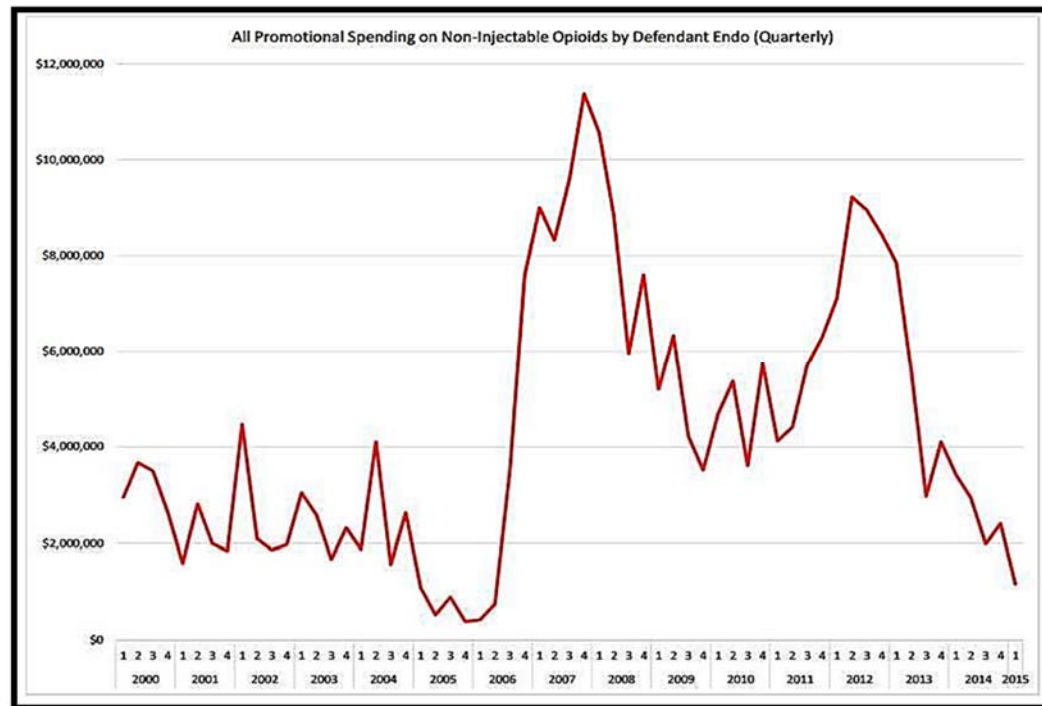
505. In accordance with common industry practice, the Marketing Defendants purchase and closely analyze prescription sales data from IMS Health (now IQVIA), a healthcare data collection, management and analytics corporation. This data allows them to track precisely the rates of initial and renewal prescribing by individual doctors, which allows them to target and tailor their appeals. Sales representatives visited hundreds of thousands of doctors and disseminated the misinformation and materials described above.

506. The Marketing Defendants devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, the Marketing Defendants spent \$166 million on detailing branded opioids to doctors. This amount is twice as much as the Marketing Defendants spent on detailing in 2000. The amount includes \$108 million spent by Purdue, \$34 million by Janssen, \$13 million by Teva, and \$10 million by Endo.

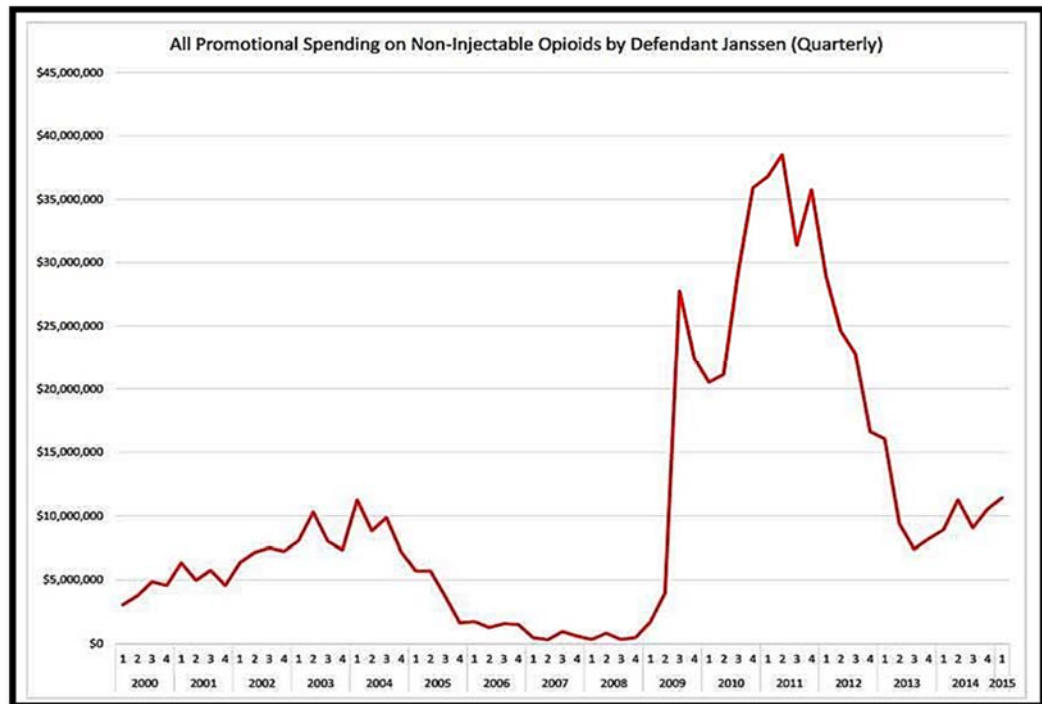
507. Cephalon's quarterly spending steadily climbed from below \$1 million in 2000 to more than \$3 million in 2014 (and more than \$13 million for the full year), with a peak, coinciding with the launch of Fentora, of more than \$27 million in 2007, as shown below:



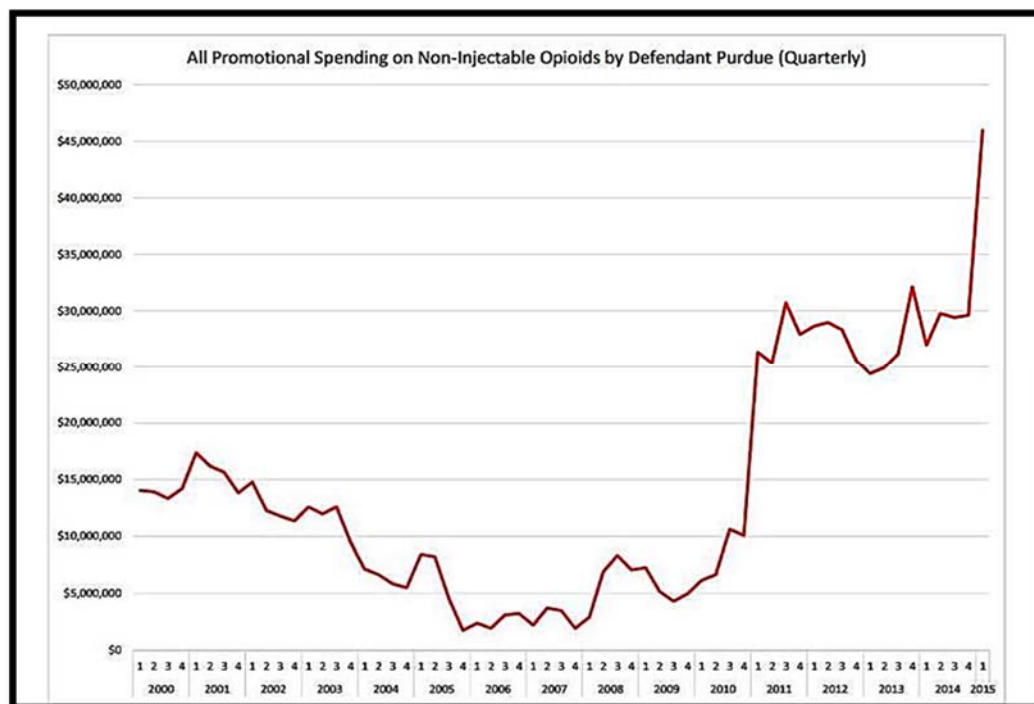
508. Endo's quarterly spending went from the \$2 million to \$4 million range in 2000-2004 to more than \$10 million following the launch of Opana ER in mid-2006 (and more than \$38 million for the year in 2007) and more than \$8 million coinciding with the launch of a reformulated version in 2012 (and nearly \$34 million for the year):



509. Janssen's quarterly spending dramatically rose from less than \$5 million in 2000 to more than \$30 million in 2011, coinciding with the launch of Nucynta ER (with yearly spending at \$142 million for 2011), as shown below:



510. Purdue's quarterly spending notably decreased from 2000 to 2007, as Purdue came under investigation by the DOJ, but then spiked to above \$25 million in 2011 (for a total of \$110 million that year), and continues to rise, as shown below:



1 511. For its opioid, Actiq, Cephalon also engaged in direct marketing in direct
2 contravention of the FDA's strict instructions that Actiq be prescribed only to terminal cancer
3 patients and by oncologists and pain management doctors experienced in treating cancer pain.

4 512. Thousands of prescribers attended Cephalon speaking programs. Cephalon tracked
5 the impact that these programs had on prescribing in the three months following the event and
6 concluded that doctors' prescribing of Fentora often increased.

7
8 **h. The Marketing Defendants Used Speakers' Bureaus
and Programs to Spread Their Deceptive Messages**

9 513. In addition to making sales calls, the Marketing Defendants' detailers also identified
10 doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and
11 meals paid for by the Marketing Defendants. These speaker programs and associated speaker
12 trainings serve three purposes: they provide an incentive to doctors to prescribe, or increase their
13 prescriptions of, a particular drug; to qualify to be selected a forum in which to further market to the
14 speaker himself or herself; and an opportunity to market to the speaker's peers. The Marketing
15 Defendants grade their speakers, and future opportunities are based on speaking performance, post-
16 program sales, and product usage. Purdue, Janssen, Endo, Cephalon, and Mallinckrodt each made
17 thousands of payments to physicians nationwide, including those related to opioids, for activities
18 including participating on speakers' bureaus, providing consulting services, and other services.
19

20
21 514. As detailed below, Insys paid prescribers for *fake* speakers programs in exchange for
22 prescribing its product, Subsys. Insys's schemes resulted in countless speakers programs at which
23 the designated speaker did not speak, and, on many occasions, speakers programs at which the only
24 attendees at the events were the speaker and an Insys sales representative. It was a pay-to-prescribe
25 program.
26

27 515. Insys used speakers programs as a front to pay for prescriptions, and paid to push
28 opioids onto patients who did not need them.

3. The Marketing Defendants Targeted Vulnerable Populations

516. The Marketing Defendants specifically targeted their marketing at two vulnerable populations – the elderly and veterans.

517. Elderly patients taking opioids have been found to be exposed to elevated fracture risks, a greater risk for hospitalizations, and increased vulnerability to adverse drug effects and interactions, such as respiratory depression which occurs more frequently in elderly patients.

518. The Marketing Defendants promoted the notion – without adequate scientific foundation – that the elderly are particularly unlikely to become addicted to opioids. The 2009 AGS Guidelines, for example, which Purdue, Endo, and Janssen publicized, described the risk of addiction as “*exceedingly low* in older patients with no current or past history of substance abuse.” As another example, an Endo-sponsored CME put on by NIPC, *Persistent Pain in the Older Adult*, taught that prescribing opioids to older patients carried “possibly less potential for abuse than in younger patients.” Contrary to these assertions, however, a 2010 study examining overdoses among long-term opioid users found that patients 65 or older were among those with the largest number of serious overdoses.

519. Similarly, Endo targeted marketing of Opana ER towards patients over 55 years old. Such documents show Endo treated Medicare Part D patients among the “most valuable customer segments.” However, in 2013, one pharmaceutical benefits management company recommended against the use of Opana ER for elderly patients and unequivocally concluded that, “[f]or patients 65 and older these medications are not safe, so consult your doctor.”

520. According to a study published in the 2013 *Journal of American Medicine*, veterans returning from Iraq and Afghanistan who were prescribed opioids have a higher incidence of adverse clinical outcomes, such as overdoses and self-inflicted and accidental injuries. A 2008 survey showed that prescription drug misuse among military personnel doubled from 2002 to 2005, and

1 then nearly tripled again over the next three years. Veterans are twice as likely as non-veterans to
 2 die from an opioid overdose.

3 521. Yet the Marketing Defendants deliberately targeted veterans with deceptive
 4 marketing. For example, a 2009 publication sponsored by Purdue, Endo, and Janssen, and
 5 distributed by APF with grants from Janssen and Endo, was written as a personal narrative of one
 6 veteran but was in fact another vehicle for opioid promotion. Called *Exit Wounds*, the publication
 7 describes opioids as “underused” and the “gold standard of pain medications” while failing to
 8 disclose significant risks of opioid use, including the risks of fatal interactions with benzodiazepines.
 9 According to a VA Office of Inspector General Report, 92.6% of veterans who were prescribed
 10 opioid drugs were also prescribed benzodiazepines, despite the increased danger of respiratory
 11 depression from the two drugs together.
 12

13 522. Opioid prescriptions have dramatically increased for veterans and the elderly. Since
 14 2007, prescriptions for the elderly have grown at twice the rate of prescriptions for adults between
 15 the ages of 40 and 59. And in 2009, military doctors wrote 3.8 million prescriptions for narcotic
 16 pain pills – four times as many as they did in 2001.
 17

18 **4. Insys Employed Fraudulent, Illegal, and Misleading Marketing** 19 **Schemes to Promote Subsys**

20 523. Insys’s opioid, Subsys, was approved by the FDA in 2012 for “management of
 21 breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-
 22 the-clock opioid therapy for their underlying persistent cancer pain.” Under FDA rules, Insys could
 23 only market Subsys for this use. Subsys consists of the highly addictive narcotic fentanyl,
 24 administered via a sublingual (under the tongue) spray, which provides rapid-onset pain relief. It is
 25 in the class of drugs described as Transmucosal Immediate-Release Fentanyl (“TIRF”).
 26

27 524. To reduce the risk of abuse, misuse, and diversion, the FDA instituted a Risk
 28 Evaluation and Mitigation Strategy (“REMS”) for Subsys and other TIRF products, such as

1 Cephalon’s Actiq and Fentora. The purpose of REMS was to educate “prescribers, pharmacists, and
 2 patients on the potential for misuse, abuse, addiction, and overdose” for this type of drug and to
 3 “ensure safe use and access to these drugs for patients who need them.”¹⁹² Prescribers must enroll in
 4 the TIRF REMS before writing a prescription for Subsys.

5
 6 525. Since its launch, Subsys has been an extremely expensive medication, and its price
 7 continues to rise each year. Depending on a patient’s dosage and frequency of use, a month’s supply
 8 of Subsys could cost in the thousands of dollars.

9 526. Due to its high cost, in most instances prescribers must submit Subsys prescriptions to
 10 insurance companies or health benefit payors for prior authorization to determine whether they will
 11 pay for the drug prior to the patient attempting to fill the prescription. According to the U.S. Senate
 12 Homeland Security and Governmental Affairs Committee Minority Staff Report, the prior
 13 authorization process includes “confirmation that the patient had an active cancer diagnosis, was
 14 being treated by an opioid (and, thus, was opioid tolerant), and was being prescribed Subsys to treat
 15 breakthrough pain that the other opioid could not eliminate. If any one of these factors was not
 16 present, the prior authorization would be denied.”¹⁹³

17
 18 527. These prior authorization requirements proved to be daunting. Subsys received
 19 reimbursement approval in only approximately 30% of submitted claims. In order to increase
 20 approvals, Insys created a prior authorization unit, called the Insys Reimbursement Center, to obtain
 21 approval for Subsys reimbursements. This unit employed a number of fraudulent and misleading
 22 tactics to secure reimbursements, including falsifying medical histories of patients, falsely claiming
 23

24 ¹⁹² Press Release, U.S. Food & Drug Admin., *FDA Approves Shared System REMS for TIRF*
 25 *Products* (Dec. 29, 2011).

26 ¹⁹³ U.S. Senate Homeland Sec. & Governmental Aff. Committee, Ranking Members’ Office,
 27 *Fueling an Epidemic*, at 2 (last visited Mar. 12, 2020),
 28 <https://www.hsgac.senate.gov/imo/media/doc/REPORT%20-%20Fueling%20an%20Epidemic%20-%20Insys%20Therapeutics%20and%20the%20Systemic%20Manipulation%20of%20Prior%20Auth%20orization.pdf>.

1 that patients had cancer, and providing misleading information to insurers and payors regarding
2 patients' diagnoses and medical conditions.

3 528. Subsys has proved to be extremely profitable for Insys. Insys made approximately
4 \$330 million in net revenue from Subsys last year. Between 2013 and 2016, the value of Insys stock
5 rose 296%.

6
7 529. Since its launch in 2012, Insys aggressively worked to grow its profits through
8 fraudulent, illegal, and misleading tactics, including its reimbursement-related fraud. Through its
9 sales representatives and other marketing efforts, Insys deceptively promoted Subsys as safe and
10 appropriate for uses such as neck and back pain, without disclosing the lack of approval or evidence
11 for such uses, and misrepresented the appropriateness of Subsys for treatment of those conditions. It
12 implemented a kickback scheme wherein it paid prescribers for fake speakers programs in exchange
13 for prescribing Subsys. All of these fraudulent and misleading schemes had the effect of pushing
14 Insys's dangerous opioid onto patients who did not need it.

15
16 530. Insys incentivized its sales force to engage in illegal and fraudulent conduct. Many of
17 the Insys sales representatives were new to the pharmaceutical industry and their base salaries were
18 low compared to industry standard. The compensation structure was heavily weighted toward
19 commissions and rewarded reps more for selling higher (and more expensive) doses of Subsys, a
20 "highly unusual" practice because most companies consider dosing a patient-specific decision that
21 should be made by a doctor.¹⁹⁴

22
23 531. The Insys "speakers program" was perhaps its most widespread and damaging
24 scheme. A former Insys salesman, Ray Furchak, alleged in a *qui tam* action that the sole purpose of
25 the speakers program was "in the words of his then supervisor Alec Burlakoff, 'to get money in the
26 doctor's pocket.'" Furchak went on to explain that "[t]he catch . . . was that doctors who increased

27
28 ¹⁹⁴ *Id.*

1 the level of Subsys prescriptions, and at higher dosages (such as 400 or 800 micrograms instead of
 2 200 micrograms), would receive the invitations to the program – and the checks.”¹⁹⁵ It was a pay-to-
 3 prescribe program.

4 532. Insys’s sham speakers program and other fraudulent and illegal tactics have been
 5 outlined in great detail in indictments and guilty pleas of Insys executives, employees, and
 6 prescribers across the country, as well as in a number of lawsuits against the company itself.

7 533. In May of 2015, two Alabama pain specialists were arrested and charged with illegal
 8 prescription drug distribution, among other charges. The doctors were the top prescribers of Subsys,
 9 though neither were oncologists. According to prosecutors, the doctors received illegal kickbacks
 10 from Insys for prescribing Subsys. Both doctors had prescribed Subsys to treat neck, back, and joint
 11 pain. In February of 2016, a former Insys sales manager pled guilty to conspiracy to commit health
 12 care fraud, including engaging in a kickback scheme in order to induce one of these doctors to
 13 prescribe Subsys. The plea agreement states that nearly all of the Subsys prescriptions written by the
 14 doctor were off-label to non-cancer patients. In May of 2017, one of the doctors was sentenced to 20
 15 years in prison.

16 534. In June of 2015, a nurse practitioner in Connecticut described as the state’s highest
 17 Medicare prescriber of narcotics, pled guilty to receiving \$83,000 in kickbacks from Insys for
 18 prescribing Subsys. Most of her patients were prescribed the drug for chronic pain. Insys paid the
 19 nurse as a speaker for more than 70 dinner programs at approximately \$1,000 per event; however,
 20 she did not give any presentations. In her guilty plea, the nurse admitted receiving the speaker fees
 21 in exchange for writing prescriptions for Subsys.

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 27 ¹⁹⁵ Roddy Boyd, *Insys Therapeutics and the New ‘Killing It,’* The Foundation for Financial
 28 Journalism (Apr. 24, 2015), <http://ffj-online.org/2015/04/24/the-new-killing-it/>.

1 535. In August of 2015, Insys settled a complaint brought by the Oregon Attorney General.
 2 In its complaint, the Oregon Department of Justice cited Insys for, among other things,
 3 misrepresenting to doctors that Subsys could be used to treat migraines, neck pain, back pain, and for
 4 other uses for which Subsys is neither safe nor effective, and using speaking fees as kickbacks to
 5 incentivize doctors to prescribe Subsys.
 6

7 536. In August of 2016, the State of Illinois sued Insys for similar deceptive and illegal
 8 practices. The complaint alleged that Insys marketed Subsys to high-volume prescribers of opioid
 9 drugs instead of to oncologists whose patients experienced the breakthrough cancer pain for which
 10 the drug is indicated. The Illinois complaint also detailed how Insys used its speaker program to pay
 11 high volume prescribers to prescribe Subsys. The speaker events took place at upscale restaurants in
 12 the Chicago area, and speakers received an “honorarium” ranging from \$700 to \$5,100 and were
 13 allowed to order as much food and alcohol as they wanted. At most of the events, the “speaker”
 14 being paid by Insys did not speak, and, on many occasions, the only attendees at the events were the
 15 speaker and an Insys sales representative.
 16

17 537. In December of 2016, six Insys executives and managers were indicted, and in
 18 October 2017, Insys’s founder and owner was arrested and charged with multiple felonies in
 19 connection with an alleged conspiracy to bribe practitioners to prescribe Subsys and defraud
 20 insurance companies. A DOJ press release explained that, among other things: “‘Insys executives
 21 improperly influenced health care providers to prescribe a powerful opioid for patients who did not
 22 need it, and without complying with FDA requirements, thus putting patients at risk and contributing
 23 to the current opioid crisis.’”¹⁹⁶ A DEA Special Agent in Charge further explained that:
 24 “‘Pharmaceutical companies whose products include controlled medications that can lead to
 25

26 ¹⁹⁶ U.S. Dep’t of Just., U.S. Attorney’s Office, Dist. of Mass., *Founder and Owner of*
 27 *Pharmaceutical Company Insys Arrested and Charged with Racketeering* (Oct. 26, 2017),
 28 <https://www.justice.gov/usao-ma/pr/founder-and-owner-pharmaceutical-company-insys-arrested-and-charged-racketeering>.

addiction and overdose have a special obligation to operate in a trustworthy, transparent manner, because their customers' health and safety and, indeed, very lives depend on it."¹⁹⁷

5. The Marketing Defendants' Scheme Succeeded, Creating a Public Health Epidemic

a. The Marketing Defendants Dramatically Expanded Opioid Prescribing and Use

538. The Marketing Defendants necessarily expected a return on the enormous investment they made in their deceptive marketing scheme and worked to measure and expand their success. Their own documents show that they knew they were influencing prescribers and increasing prescriptions. Studies also show that in doing so, they fueled an epidemic of addiction and abuse.

539. Endo, for example, directed the majority of its marketing budget to sales representatives – with good results: 84% of its prescriptions were from the doctors they detailed. Moreover, as of 2008, cancer and post-operative pain accounted for only 10% of Opana ER's uses; virtually all of Endo's opioid sales – and profits – were from a market that did not exist ten years earlier. Internal emails from Endo staff attributed increases in Opana ER sales to the aggressiveness and persistence of sales representatives. Similarly, according to an internal Janssen training document, sales representatives were told that sales calls and call intensity have a high correlation to sales.

540. Cephalon also recognized the return on its efforts to market Actiq and Fentora off-label for chronic pain. In 2000, Actiq generated \$15 million in sales. By 2002, Actiq sales had increased by 92%, which Cephalon attributed to "a dedicated sales force for ACTIQ" and "ongoing changes to [its] marketing approach including hiring additional sales representatives and targeting our marketing efforts to pain specialists."¹⁹⁸ Actiq became Cephalon's second-best-selling drug. By

¹⁹⁷ *Id.*

¹⁹⁸ Cephalon, Inc., Annual Report (Form 10-K) at 28 (Mar. 31, 2003), <https://www.sec.gov/Archives/edgar/data/873364/000104746903011137/a2105971z10-k.htm>.

1 the end of 2006, Actiq's sales had exceeded \$500 million. Only 1% of the 187,076 prescriptions for
2 Actiq filled at retail pharmacies during the first six months of 2006 were prescribed by oncologists.
3 By one measure, "more than 80 [percent] of patients who use[d] the drug don't have cancer."¹⁹⁹

4 541. Upon information and belief, each of the Marketing Defendants tracked the impact of
5 their marketing efforts to measure their impact in changing doctors' perceptions and prescribing of
6 their drugs. They purchased prescribing and survey data that allowed them to closely monitor these
7 trends, and they did actively monitor them. They monitored doctors' prescribing before and after
8 detailing visits, and at various levels of detailing intensity, and before and after speakers programs,
9 for instance. Defendants continued and, in many cases, expanded and refined their aggressive and
10 deceptive marketing for one reason: it worked. As described in this complaint, both in specific
11 instances (*e.g.*, the low abuse potential of various Defendants' opioids), and more generally,
12 Defendants' marketing changed prescribers' willingness to prescribe opioids, led them to prescribe
13 more of their opioids, and persuaded them not to stop prescribing opioids or to switch to "safer"
14 opioids, such as ADF opioids.
15

16
17 542. This success would have come as no surprise. Drug company marketing materially
18 impacts doctors' prescribing behavior. The effects of sales calls on prescribers' behavior is well
19 documented in the literature, including a 2017 study that found that physicians ordered fewer
20 promoted brand-name medications and prescribed more cost-effective generic versions if they
21 worked in hospitals that instituted rules about when and how pharmaceutical sales representatives
22 were allowed to detail prescribers. The changes in prescribing behavior appeared strongest at
23 hospitals that implemented the strictest detailing policies and included enforcement measures.
24 Another study examined four practices, including visits by sales representatives, medical journal
25

26
27 ¹⁹⁹ John Carreyrou, *Narcotic "Lollipop" Becomes Big Seller Despite FDA Curbs*, Wall St. J. (Nov.
28 3, 2006), <https://www.opiates.com/media/narcotic-lollipop-becomes-big-seller-despitefda-curbs/>.

1 advertisements, direct-to-consumer advertising, and pricing, and found that sales representatives
 2 have the strongest effect on drug utilization. An additional study found that doctor meetings with
 3 sales representatives are related to changes in both prescribing practices and requests by physicians
 4 to add the drugs to hospitals' formularies.

5
 6 543. The Marketing Defendants spent millions of dollars to market their drugs to
 7 prescribers and patients and meticulously tracked their return on that investment. In one recent
 8 survey published by the AMA, even though nine in ten general practitioners reported prescription
 9 drug abuse to be a moderate to large problem in their communities, 88% of the respondents said they
 10 were confident in their prescribing skills, and nearly half were comfortable using opioids for chronic
 11 non-cancer pain. These results are directly due to the Marketing Defendants' fraudulent marketing
 12 campaign focused on several misrepresentations.

13
 14 544. Thus, both independent studies and the Marketing Defendants' own tracking confirm
 15 that Defendants' marketing scheme dramatically increased their sales.

16 **b. The Marketing Defendants' Deception in Expanding**
 17 **Their Market Created and Fueled the Opioid Epidemic**

18 545. Independent research demonstrates a close link between opioid prescriptions and
 19 opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic
 20 exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."²⁰⁰ It has been
 21 estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians'
 22 prescriptions.

23 546. There is a parallel relationship between the availability of prescription opioid
 24 analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and
 25

26
 27 ²⁰⁰ Theodore J. Cicero *et al.*, *Relationship Between Therapeutic Use and Abuse of Opioid*
 28 *Analgesics in Rural, Suburban, and Urban Locations in the United States*, 16(8)
Pharmacopidemiology and Drug Safety 827-40 (2007).

1 associated adverse outcomes. The opioid epidemic is “directly related to the increasingly
2 widespread misuse of powerful opioid pain medications.”²⁰¹

3 **E. Defendants, Throughout the Supply Chain, Deliberately Disregarded**
4 **Their Duties to Maintain Effective Controls and to Identify, Report,**
5 **and Take Steps to Halt Suspicious Orders**

6 547. The marketing defendants created a vastly and dangerously larger market for opioids.
7 All of the Defendants compounded this harm by facilitating the supply of far more opioids that could
8 have been justified to serve that market. The failure of the Defendants to maintain effective controls,
9 and to investigate, report, and take steps to halt orders that they knew or should have known were
10 suspicious breached both their statutory and common law duties.

11 548. For over a decade, as the Marketing Defendants increased the demand for opioids, all
12 of the Defendants aggressively sought to bolster their revenue, increase profit, and grow their share
13 of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of
14 opioids they sold. However, Defendants are not permitted to engage in a limitless expansion of their
15 sales through the unlawful sales of regulated painkillers. Rather, as described below, Defendants are
16 subject to various duties to report the quantity of Schedule II controlled substances in order to
17 monitor such substances and prevent oversupply and diversion into the illicit market.

18 549. Defendants are all required to register as either manufacturers or distributors pursuant
19 to 21 U.S.C. §823 and 21 C.F.R. §§1301.11, 1301.74.

20 550. The Marketing Defendants’ scheme was resoundingly successful. Chronic opioid
21 therapy – the prescribing of opioids long term to treat chronic pain – has become a commonplace,
22 and often first-line, treatment. The Marketing Defendants’ deceptive marketing caused prescribing
23 not only of their opioids, but of opioids as a class, to skyrocket. According to the CDC, opioid
24 prescriptions, as measured by the number of prescriptions and MME per person, tripled from 1999 to
25

26
27 ²⁰¹ Robert M. Califf, M.D., *et al.*, *A Proactive Response to Prescription Opioid Abuse*, New Eng. J.
28 Med., 1480-85 (2016), <http://www.nejm.org/doi/full/10.1056/NEJMSr1601307>.

1 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the
 2 United States. While previously a small minority of opioid sales, today between 80% and 90% of
 3 opioids (measured by weight) are used are for chronic pain. Approximately 20% of the population
 4 between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids.
 5 Opioids are the most common treatment for chronic pain, and 20% of office visits now include the
 6 prescription of an opioid.
 7

8 551. In a 2016 report, the CDC explained that “[o]pioid pain reliever prescribing has
 9 quadrupled since 1999 and has increased in parallel with [opioid] overdoses.” Patients receiving
 10 opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the
 11 CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical “[t]o
 12 reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity.”²⁰²
 13

14 **1. Acting as Both a Wholesale Distributor and Operator of Retail**
 15 **Pharmacies in San Francisco, Walgreens Failed to Uphold Its**
 16 **Obligations Both to Report Suspicious Orders and to Stop**
 17 **Filling “Red Flag” Prescriptions**

18 552. Walgreens is the second-largest pharmacy store chain in the United States behind
 19 CVS, with annual revenue of more than \$136.9 billion in fiscal year 2019, ranking 17th on the
 20 Fortune 500 list.²⁰³ According to Walgreens’ 2019 Annual Report, Walgreens operates 9,277 retail
 21 pharmacies in the United States and filled 1.2 billion prescriptions on a 30-day adjusted basis in
 22
 23
 24

25 ²⁰² *Increases in Drug and Opioid Overdose Deaths- United States, 2000-2014*, Ctrs. For Disease
 26 Control and Prevention (Jan. 1, 2016), <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm>

27 ²⁰³ Walgreens Boots Alliance, Annual Report 2019, at 1 (Oct. 28, 2019), https://s1.q4cdn.com/343380161/files/doc_financials/2019/annual/2019-Annual-Report-Final.pdf
 28

1 fiscal year 2019.²⁰⁴ As of March 2020, Walgreens operated 57 retail pharmacy locations in San
 2 Francisco, making it by far the largest retail pharmacy operator in San Francisco.²⁰⁵

3 553. Until mid-2014, Walgreens was not only a major dispenser of opioids, but also a
 4 major wholesale distributor of opioids. Specifically, Walgreens was the intermediary between
 5 opioid manufacturers and its large network of retail pharmacies. Like the other Distributor
 6 Defendants, Walgreens warehoused opioids in distribution centers and, in response to orders from its
 7 retail pharmacies, dispatched shipments of large stocks of opioids to enable its retail locations to
 8 fulfill increasing volumes of opioid prescriptions over time.

10 554. According to the DOJ's Automated Reports and Consolidated Ordering System
 11 ("ARCOS"), which tracks controlled substances transactions, from 2006 to 2014 Walgreens
 12 maintained the highest market share in San Francisco both in terms of opioid distribution and
 13 dispensing. During this time period, Walgreens' distribution market share was 33.7%, followed by
 14 McKesson at 27.9%, AmerisourceBergen at 17.9%, and Cardinal at 7.4%. Walgreens' dispensing
 15 market share, measured in terms of the percentage of all San Francisco opioid pills dispensed, was
 16 55.5%, with no other dispenser exceeding 10% market share. On information and belief, Walgreens
 17 remains the single largest dispenser of opioids in San Francisco to this day.

19 555. Walgreens earned enormous profits by flooding San Francisco with prescription
 20 opioids. Walgreens was keenly aware of the oversupply of prescription opioids through the
 21 extensive data and information it developed and maintained as both a distributor and dispenser. Yet,
 22 instead of taking any meaningful action to stem the flow of opioids into San Francisco, Walgreens
 23 continued to participate in the oversupply and profit from it. Walgreens failed to take meaningful
 24

26 ²⁰⁴ *Id.* at 5.

27 ²⁰⁵ See Walgreens, *Find a store*, [https://www.walgreens.com/storelocator/find.jsp?tab=store+](https://www.walgreens.com/storelocator/find.jsp?tab=store+locator&requestType=locator)
 28 [locator&requestType=locator](https://www.walgreens.com/storelocator/find.jsp?tab=store+locator&requestType=locator) (last visited Mar. 5, 2020).

1 action to stop diversion despite its knowledge of it, and Walgreens also contributed substantially to
2 the diversion problem itself.

3 556. Walgreens developed and maintained extensive data on opioids it distributed and
4 dispensed. With the data, Walgreens had direct knowledge of patterns and instances of improper
5 distribution, prescribing, and use of prescription opioids in communities throughout the country, and
6 in San Francisco in particular. Walgreens used the data to evaluate its own sales activities and
7 workforce. On information and belief, Walgreens also provided other Defendants with data
8 regarding, *inter alia*, individual doctors in exchange for rebates or other forms of consideration.
9 Walgreens dataset was (and continues to be) a valuable resource that it could use to help stop
10 diversion, but it has failed to do so.

12 557. Each participant in the opioid supply chain, including the pharmacy itself, is
13 responsible for preventing diversion of prescription opioids into the illegal market by, among other
14 things, monitoring, reporting suspicious activity, and refusing to fill invalid prescriptions.

16 558. Walgreens' distribution operation was required to operate in accordance with the
17 statutory provisions of the CSA and the regulations promulgated thereunder, 21 C.F.R. §1300 *et seq.*
18 The regulations promulgated under the CSA include a requirement to design and operate a system to
19 detect and report "suspicious orders" for controlled substances. *See* 21 C.F.R. §1301.74(b). The
20 CSA authorizes the imposition of a civil penalty of up to \$10,000 for each violation of 21 C.F.R.
21 §1301.74(b). *See* 21 U.S.C. §842(a)(5), (c)(1)(B).

23 559. Just as manufacturers and distributors must register under the CSA, so, too, must
24 pharmacies. 21 C.F.R. §1301.11. Under the CSA, pharmacists are charged with a "corresponding
25 responsibility" to dispense only legitimate prescriptions and implement effective controls and
26 procedures to prevent diversion. *See* 21 C.F.R. §§1306.04(a), 1301.71(a). That "'corresponding
27 responsibility' . . . means, among other things, that a pharmacist is obligated to refuse to fill a
28

1 prescription if he knows *or has reason to know* that the prescription was not written for a legitimate
 2 medical purpose.” *Medic-Aid Pharmacy, Revocation of Registration*, 55 Fed. Reg. 30,043, 30,044
 3 (July 24, 1990) (emphasis added). Notably, “pharmacists do not need to practice medicine or
 4 independently examine a patient in order to determine in certain cases that a prescription was not
 5 issued for a legitimate medical purpose.” *Jones Total Health Care Pharmacy, LLC v. Drug Enf’t*
 6 *Admin.*, 881 F.3d 823, 832 (11th Cir. 2018). “When [pharmacists’] suspicions are aroused as
 7 reasonable professionals . . . pharmacists are called upon to obey the law and refuse to dispense.”
 8 *Ralph J. Bertolino*, 55 Fed. Reg. 4,729, 4,730 (Feb. 9, 1990); *see also Grider Drug #1 & Grider*
 9 *Drug #2; Decision and Order*, 77 Fed. Reg. 44,069 (July 26, 2012).

11 560. Pharmacy owners, including large retail pharmacy corporations like Walgreens, are
 12 also liable for their pharmacists’ CSA violations. *See, e.g., United States v. Appalachian Reg’l*
 13 *Healthcare, Inc.*, 246 F. Supp. 3d 1184, 1189 (E.D. Ky. Mar. 30, 2017); *Holiday CVS, L.L.C., d/b/a*
 14 *CVS/Pharmacy Nos. 209 & 5195, Decision and Order*, 77 Fed. Reg. 62,316, 62,323 (Oct. 12, 2012)
 15 (“[T]he fact that CVS is a large corporation provides no reason to excuse it from explicitly
 16 acknowledging the misconduct of Respondents and their pharmacists.”).

18 561. The DEA, among others, has provided extensive guidance to pharmacies concerning
 19 their duties to the public. The guidance advises pharmacies how to identify suspicious orders and
 20 other evidence of diversion. Suspicious pharmacy orders include orders of unusually large size,
 21 orders that are disproportionately large in comparison to the population of a community served by
 22 the pharmacy, orders that deviate from a normal pattern, and/or orders of unusual frequency and
 23 duration, among others.

25 562. Suspicious pharmacy orders are often termed “red flags” because they are evidence of
 26 diversion. Additional “red flags” include: (1) prescriptions written by a doctor who writes
 27 significantly more prescriptions (or in larger quantities or higher doses) for controlled substances
 28

1 compared to other practitioners in the area; (2) prescriptions that should last for a month in
2 legitimate use but are being refilled on a shorter basis; (3) prescriptions for antagonistic drugs, such
3 as depressants and stimulants, at the same time; (4) prescriptions that look “too good” or where the
4 prescriber’s handwriting is *too* legible; (5) prescriptions with quantities or doses that differ from
5 usual medical usage; (6) prescriptions that do not comply with standard abbreviations and/or contain
6 no abbreviations; (7) photocopied prescriptions; or (8) prescriptions containing different
7 handwriting. Most of the time, these attributes are not difficult to detect and should be easily
8 recognizable by pharmacies.
9

10 563. Other signs of diversion could be observed through data gathered, consolidated, and
11 analyzed by Walgreens. Data allowed Walgreens to observe patterns or instances of dispensing that
12 were potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers
13 or facilities that appeared to engage in improper prescribing.
14

15 564. According to industry standards, if a pharmacy finds evidence of prescription
16 diversion, the local Board of Pharmacy and DEA must be contacted. Despite this and legal
17 obligations as a registrant under the CSA, Walgreens allowed widespread diversion to occur – and it
18 did so knowingly.
19

20 565. Performance metrics and prescription quotas Walgreens adopted for its retail stores
21 contributed to its failure. Through its compensation system, Walgreens pharmacists were
22 incentivized to meet high prescription-filling goals that made it difficult, if not impossible, to comply
23 with applicable laws and regulations. These policies remained in place even as the epidemic raged.
24

25 566. This problem was compounded by Walgreens’ failure to adequately train its
26 pharmacists and pharmacy technicians on the following non-exhaustive topics: (a) what constitutes a
27 proper inquiry into whether an opioid prescription is legitimate; (b) whether an opioid prescription is
28 likely for an FDA-approved condition; (c) what measures and/or actions should be taken when a

1 prescription is identified as phony, false, forged, or otherwise illegal; and (d) how to respond to
2 suspicious circumstances, including indications that pills are being illegally diverted, including into
3 drug trafficking.

4 567. Upon information and belief, Walgreens also failed to adequately use data available
5 to it to identify doctors who were writing suspicious volumes of prescriptions and/or prescriptions
6 for suspicious amounts of opioids, or to adequately use data available to it to do statistical analysis to
7 avoid filling prescriptions that were illegally diverted or otherwise contributed to the opioid crisis.
8

9 568. Upon information and belief, Walgreens failed to analyze: (a) the number of opioid
10 prescriptions filled by individual pharmacies relative to the population of the pharmacies'
11 communities; (b) the increase in opioid sales relative to past years; (c) the number of opioid
12 prescriptions filled relative to other drugs; and (d) the increase in annual opioid sales relative to the
13 increase in annual sales of other drugs.
14

15 569. Walgreens also failed to conduct adequate internal or external audits of its opioid
16 sales to identify patterns regarding prescriptions that should not have been filled and to create
17 policies accordingly, and Walgreens failed to take any meaningful action as a result of its limited
18 auditing.

19 570. Walgreens also failed to effectively respond to concerns raised by its own employees
20 regarding inadequate policies and procedures regarding opioid dispensing.
21

22 571. Walgreens was, or should have been, fully aware that the quantity of opioids it was
23 both distributing and dispensing was untenable, and in many respects, patently absurd, yet
24 Walgreens did not take meaningful action to investigate or to ensure that it was complying with its
25 duties and obligations under the law with regard to controlled substances. For example, some
26 pharmacies nationally saw increases in opioid orders of as much as 600% in the span of two years.
27
28

1 Walgreens even supplied a town of 3,000 with 285,800 orders of oxycodone in a one-month
2 period.²⁰⁶

3 572. Walgreens' pattern, whether as a distributor or dispenser, of prioritizing profit derived
4 from increased opioid volume over the well-being of the San Francisco community dates back to at
5 least the late 1990s, when Walgreens adopted pharmacist training modules developed by opioid
6 manufacturer Purdue, despite the clear conflict of interest. The chronology of Walgreens'
7 misconduct includes, but is not limited, to the facts below:

9 573. In 2006, the DEA sent a Letter of Admonition to Walgreens regarding record-keeping
10 and security inadequacies at a major distribution facility. The DEA soon took issue with Walgreens'
11 practice of impeding the DEA's oversight role by regularly providing what amounted to an
12 unmanageable "data dump" of all potentially suspicious opioid transactions rather than only those
13 transactions that Walgreens could not reclassify after a diligent review.

15 574. By 2009, the DEA had issued an Order to Show Cause regarding dispensing practices
16 at a San Diego pharmacy, noting that Walgreens had provided no training internally for employees
17 dispensing controlled substances. That year Walgreens implemented a Suspicious Order Monitoring
18 program to identify pharmacy distribution orders that exceeded tolerance and frequency thresholds.
19 The program, however, to which Walgreens never assigned more than 11 employees nationwide, did
20 not reduce orders that exceeded these thresholds until 2012. Even these order reductions were easily
21 defeated, as Walgreens allowed individual retail pharmacies to "interstore" – that is, to obtain
22 opioids from a second local pharmacy when the first pharmacy exceeded its opioid order threshold.

24
25 ²⁰⁶ Representative of Walgreens' conduct nationally and in San Francisco, the Massachusetts
26 Attorney General's Medicaid Fraud Division found that, from 2010 through most of 2015, multiple
27 Walgreens stores across the state failed to monitor the opioid use of some Medicaid patients who
28 were considered high risk. Further, in January 2017, an investigation by the Massachusetts Attorney
General found that some Walgreens pharmacies failed to monitor patients' drug use patterns and did
not use sound professional judgment when dispensing opioids and other controlled substances –
despite soaring overdose deaths.

1 Only in 2013 did Walgreens require individual stores to affirmatively justify orders over thresholds,
2 but Walgreens approved greater than 95% of these requests in fiscal years 2014 and 2015.

3 575. Walgreens' Suspicious Order Monitoring program was not designed to succeed. This
4 is, in part, because Walgreens provided financial incentives to its pharmacists to fill an ever greater
5 volume of opioid prescriptions. In 2010, for example, Walgreens used oxycodone dispensing
6 metrics to target the managers of retail pharmacies with comparatively low dispensing figures and
7 then instructed those managers not to "turn away" customers. Similarly, in 2011, Walgreens
8 implemented a sales initiative instructing pharmacists specifically to increase their Schedule II
9 controlled substances business.
10

11 576. In 2013, Walgreens reached an historic \$80 million settlement – then the largest DEA
12 settlement ever – to resolve allegations that it violated the CSA. As part of that agreement,
13 Walgreens acknowledged that "certain Walgreens retail pharmacies did on some occasions dispense
14 certain controlled substances in a manner not fully consistent with its compliance obligations under
15 the CSA . . . and its implementing regulations."²⁰⁷ Walgreens agreed to exclude controlled substance
16 prescriptions from bonus calculations for pharmacists, but prescription filling volume was still
17 considered in bonus metrics – meaning that pharmacists doing their due diligence to resolve
18 suspicious "red flags" associated with opioid prescriptions had less time to fill other prescriptions
19 considered for their bonuses. Walgreens also agreed to cease distribution of opioids at certain
20 facilities, and in 2014 Walgreens ceased distribution of opioids altogether.
21
22

23 577. Nevertheless, Walgreens' illegal opioid dispensing practices continued even after its
24 historic settlement with the federal government. In 2015, Walgreens performed an audit of 2,400
25 pharmacies and found that, during a nine-month period, fewer than 60% were in compliance with its
26

27 ²⁰⁷ See Settlement and Memorandum of Agreement, *In re Nat'l Prescription Opiate Litig.*, No. 1:17-
28 md-02804-DAP (N.D. Ohio Aug. 14, 2019), ECF No. 2357 at 2.

1 opioid dispensing protocols, 1,160 stores had not refused a single prescription, and only 63
 2 pharmacies had refused 26 or more prescriptions. The audit also found that over 35,000 employees
 3 had not completed their required opioid dispensing training for that year. Even those Walgreens
 4 employees who did complete their training were instructed that the presence of an unresolved “red
 5 flag” (suspicious marker) should not necessarily result in the refusal to fill an opioid prescription.
 6

7 578. Only in 2018 did Walgreens finally end its practice of including controlled substances
 8 in its prescriptions-filled-per-day metric for evaluating pharmacists. Walgreens still has not
 9 implemented adequate safeguards to ensure that its 57 retail pharmacies in San Francisco are not a
 10 conduit for diversion of opioids.

11 **2. All Defendants Have a Duty to Report Suspicious Orders and**
 12 **Not to Ship Those Orders Unless Due Diligence Disproves**
 13 **Their Suspicions**

14 579. Multiple sources impose duties on the Defendants to report suspicious orders and,
 15 further, to not ship those orders unless due diligence disproves those suspicions.

16 580. First, under the common law, the Defendants had a duty to exercise reasonable care in
 17 delivering dangerous narcotic substances. By flooding San Francisco with more opioids than could
 18 be used for legitimate medical purposes and by filling and failing to report orders that they knew or
 19 should have realized were likely being diverted for illicit uses, Defendants breached that duty and
 20 both created and failed to prevent a foreseeable risk of harm.

21 581. Second, each of the Defendants assumed a duty, when speaking publicly about
 22 opioids and their efforts to combat diversion, to speak accurately and truthfully.

23 582. Third, each of the Defendants was required to register with the DEA to manufacture
 24 and/or distribute Schedule II controlled substances. *See* 21 U.S.C. §823(a)-(b), (e); 28 C.F.R.
 25 §0.100. As registrants, Defendants were required to “maint[ain] . . . effective controls against
 26 diversion” and to “design and operate a system to disclose . . . suspicious orders of controlled
 27
 28

1 substances.” 21 U.S.C. §823(a)-(b); 21 C.F.R. §1301.74(b). Defendants were further required to
2 take steps to halt suspicious orders. Defendants violated their obligations under federal law.

3 583. Fourth, as described below, Defendants also had duties under applicable state laws.

4 584. Recognizing a need for greater scrutiny over controlled substances due to their
5 potential for abuse and danger to public health and safety, the U.S. Congress enacted the Controlled
6 Substances Act in 1970. The CSA and its implementing regulations created a closed system of
7 distribution for all controlled substances and listed chemicals. Congress specifically designed the
8 closed chain of distribution to prevent the diversion of legally produced controlled substances into
9 the illicit market. Congress was concerned with the diversion of drugs out of legitimate channels of
10 distribution and acted to halt the “widespread diversion of [controlled substances] out of legitimate
11 channels into the illegal market.”²⁰⁸ Moreover, the closed system was specifically designed to
12 ensure that there are multiple ways of identifying and preventing diversion through active
13 participation by registrants within the drug delivery chain. All registrants – which includes all
14 manufacturers and distributors of controlled substances – must adhere to the specific security,
15 record-keeping, monitoring and reporting requirements that are designed to identify or prevent
16 diversion. When registrants at any level fail to fulfill their obligations, the necessary checks and
17 balances collapse. The result is the scourge of addiction that has occurred.

18 585. The CSA requires manufacturers and distributors of Schedule II substances like
19 opioids to: (a) limit sales within a quota set by the DEA for the overall production of Schedule II
20 substances like opioids; (b) register to manufacture or distribute opioids; (c) maintain effective
21 controls against diversion of the controlled substances that they manufacture or distribute; and
22 (d) design and operate a system to identify suspicious orders of controlled substances, halt such
23 unlawful sales, and report them to the DEA.

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28 ²⁰⁸ H.R. Rep. No. 91-1444, *reprinted in* 1979 U.S.C.C.A.N. at 4572.

1 586. Central to the closed system created by the CSA was the directive that the DEA
 2 determine quotas of each basic class of Schedule I and II controlled substances each year. The quota
 3 system was intended to reduce or eliminate diversion from “legitimate channels of trade” by
 4 controlling the “quantities of the basic ingredients needed for the manufacture of [controlled
 5 substances], and the requirement of order forms for all transfers of these drugs.”²⁰⁹ When evaluating
 6 production quotas, the DEA was instructed to consider the following information:
 7

- 8 (a) Information provided by the Department of Health and Human Services;
- 9 (b) Total net disposal of the basic class of each drug by all manufacturers;
- 10 (c) Trends in the national rate of disposal of the basic class of each drug;
- 11 (d) An applicant’s production cycle and current inventory position;
- 12 (e) Total actual or estimated inventories of the class of drug and of all substances
 13 manufactured from the class and trends in inventory accumulation; and
 14
- 15 (f) Other factors such as changes in the currently accepted medical use of
 16 substances manufactured for a basic class, the economic and physical availability of raw materials,
 17 yield and sustainability issues, potential disruptions to production, and unforeseen emergencies.

18 587. It is unlawful to manufacture a controlled substance in Schedule II, like prescription
 19 opioids, in excess of a quota assigned to that class of controlled substances by the DEA.
 20

21 588. To ensure that even drugs produced within quota are not diverted, federal regulations
 22 issued under the CSA mandate that all registrants, manufacturers and distributors alike, “design and
 23 operate a system to disclose to the registrant suspicious orders of controlled substances.” 21 C.F.R.
 24 §1301.74(b). Registrants are not entitled to be passive (but profitable) observers, but rather “shall
 25 inform the Field Division Office of the Administration in his area of suspicious orders when
 26 discovered by the registrant.” *Id.* “Suspicious orders include orders of unusual size, orders
 27

28 ²⁰⁹ H.R. Rep. No. 91-1444, at 2073 (1970).

1 deviating substantially from a normal pattern, and orders of unusual frequency.” *Id.* The DEA also
2 informed registrants that other red flags may include, for example, ordering the same controlled
3 substance from multiple distributors.

4 589. These criteria are disjunctive and are not all inclusive. For example, if an order
5 deviates substantially from a normal pattern, the size of the order does not matter and the order
6 should be reported as suspicious. Likewise, a distributor or manufacturer need not wait for a normal
7 pattern to develop over time before determining whether a particular order is suspicious. The size of
8 an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the
9 responsibility to report the order as suspicious. The determination of whether an order is suspicious
10 depends not only on the ordering patterns of the particular customer but also on the patterns of the
11 entirety of the customer base and the patterns throughout the relevant segment of the industry. For
12 this reason, identification of suspicious orders serves also to identify excessive volume of the
13 controlled substance being shipped to a particular region.

14 590. In sum, Defendants have several responsibilities under state and federal law with
15 respect to control of the supply chain of opioids. First, they must set up a system to prevent
16 diversion, including excessive volume and other suspicious orders. That would include reviewing
17 their own data, relying on their observations of prescribers and pharmacies, and following up on
18 reports or concerns of potential diversion. All suspicious orders must be reported to relevant
19 enforcement authorities. Further, they must also stop shipment of any order that is flagged as
20 suspicious and only ship orders that were flagged as potentially suspicious if, after conducting due
21 diligence, they can determine that the order is not likely to be diverted into illegal channels.

22 591. State and federal statutes and regulations reflect a standard of conduct and care below
23 which reasonably prudent manufacturers and distributors would not fall. Together, these laws and
24 industry guidelines make clear that the Distributor and Marketing Defendants alike possess and are
25

1 expected to possess specialized and sophisticated knowledge, skill, information, and understanding
2 of both the market for scheduled prescription narcotics and of the risks and dangers of the diversion
3 of prescription narcotics when the supply chain is not properly controlled.

4 592. Further, these laws and industry guidelines make clear that the Distributor Defendants
5 and Marketing Defendants alike have a duty and responsibility to exercise their specialized and
6 sophisticated knowledge, information, skill, and understanding to prevent the oversupply of
7 prescription opioids and minimize the risk of their diversion into an illicit market.

8
9 593. The Federal Trade Commission (“FTC”) has recognized the unique role of
10 distributors. Since their inception, the Distributor Defendants have continued to integrate vertically
11 by acquiring businesses that are related to the distribution of pharmaceutical products and health care
12 supplies. In addition to the actual distribution of pharmaceuticals, as wholesalers, the Distributor
13 Defendants also offer their pharmacy, or dispensing, customers a broad range of added services. For
14 example, the Distributor Defendants offer their pharmacies sophisticated ordering systems and
15 access to an inventory management system and distribution facility that allows customers to reduce
16 inventory carrying costs. The Distributor Defendants are also able to use the combined purchase
17 volume of their customers to negotiate the cost of goods with manufacturers and offer services that
18 include software assistance and other database management support. *See Fed. Trade Comm’n v.*
19 *Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998) (granting the FTC’s motion for
20 preliminary injunction and holding that the potential benefits to customers did not outweigh the
21 potential anti-competitive effect of a proposed merger between Cardinal Health, Inc. and Bergen
22 Brunswig Corp.). As a result of their acquisition of a diverse assortment of related businesses within
23 the pharmaceutical industry, as well as the assortment of additional services they offer, the
24 Distributor Defendants have a unique insight into the ordering patterns and activities of their
25 dispensing customers.
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1 594. The Marketing Defendants also have specialized and detailed knowledge of the
 2 potential suspicious prescribing and dispensing of opioids through their regular visits to doctors’
 3 offices and pharmacies and from their purchase of data from commercial sources, such as IMS
 4 Health. In addition, the Marketing Defendants regularly mined data, including, upon information
 5 and belief, chargeback data, which allowed them to monitor the volume and type of prescribing of
 6 doctors, including sudden increases in prescribing and unusually high dose prescribing, which would
 7 have alerted them, independent of their sales representatives, to suspicious prescribing. These
 8 information points gave the Marketing Defendants insight into prescribing and dispensing conduct
 9 that enabled them to play a valuable role in preventing diversion and fulfilling their obligations
 10 under the CSA.
 11

12 595. Defendants have a duty, and are expected, to be vigilant in deciding whether a
 13 prospective customer can be trusted to deliver controlled substances only for lawful purposes.
 14

15 596. Defendants breached these duties by failing to: (a) control the supply chain;
 16 (b) prevent diversion; (c) report suspicious orders; and (d) halt shipments of opioids in quantities
 17 they knew or should have known could not be justified and were indicative of serious problems of
 18 overuse of opioids.
 19

20 **a. Defendants Were Aware of and Have Acknowledged**
 21 **Their Obligations to Prevent Diversion and to Report**
 22 **and Take Steps to Halt Suspicious Orders**

23 597. The reason for the reporting rules is to create a “closed” system intended to control
 24 the supply and reduce the diversion of these drugs out of legitimate channels into the illicit market,
 25 while at the same time providing the legitimate drug industry with a unified approach to narcotic and
 26 dangerous drug control. Both because distributors handle such large volumes of controlled
 27 substances and because they are uniquely positioned, based on their knowledge of their customers
 28 and orders, as the first line of defense in the movement of legal pharmaceutical controlled substances

1 from legitimate channels into the illicit market, distributors' obligation to maintain effective controls
2 to prevent diversion of controlled substances is critical. Should a distributor deviate from these
3 checks and balances, the closed system of distribution, designed to prevent diversion, collapses.

4 598. Defendants were well aware they had an important role to play in this system, and
5 also knew or should have known that their failure to comply with their obligations would have
6 serious consequences.

7 599. Mallinckrodt has admitted in a settlement with DEA that, "[a]s a registrant under the
8 CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a
9 requirement that it review and monitor these sales and report suspicious orders to DEA."
10 Mallinckrodt further stated that it "recognizes the importance of the prevention of diversion of the
11 controlled substances [it] manufacture[s]" and agreed that it would "design and operate a system that
12 meets the requirements of 21 CFR 1301.74(b) [such that it would] utilize all available transaction
13 information to identify suspicious orders of any Mallinckrodt product." Mallinckrodt specifically
14 agreed "to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt
15 controlled substances that Mallinckrodt discovers."

16 600. Trade organizations to which Defendants belong have acknowledged that wholesale
17 distributors have been responsible for reporting suspicious orders for more than 40 years. The
18 Healthcare Distribution Management Association ("HDMA," now known as the Healthcare
19 Distribution Alliance ("HDA")), a trade association of pharmaceutical distributors to which the
20 Distributor Defendants belong, has long taken the position that distributors have responsibilities to
21 "prevent diversion of controlled prescription drugs" not only because they have statutory and
22 regulatory obligations do so, but "as responsible members of society." Guidelines established by the
23 HDA also explain that distributors, "[a]t the center of a sophisticated supply chain . . . are uniquely
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1 situated to perform due diligence in order to help support the security of the controlled substances
2 they deliver to their customers.”

3 601. The DEA also repeatedly reminded Defendants of their obligations to report and
4 decline to fill suspicious orders. Responding to the proliferation of pharmacies operating on the
5 internet that arranged illicit sales of enormous volumes of opioids to drug dealers and customers, the
6 DEA began a major push to remind distributors of their obligations to prevent these kinds of abuses
7 and educate them on how to meet these obligations. Since 2007, the DEA has hosted at least five
8 conferences that provided registrants with updated information about diversion trends and regulatory
9 changes. Each of the Distributor Defendants attended at least one of these conferences. The DEA
10 has also briefed wholesalers regarding legal, regulatory, and due diligence responsibilities since
11 2006. During these briefings, the DEA pointed out the red flags wholesale distributors should look
12 for to identify potential diversion.
13

14 602. The DEA also advised in a September 27, 2006 letter to every commercial entity
15 registered to distribute controlled substances that they are “one of the key components of the
16 distribution chain. If the closed system is to function properly . . . distributors must be vigilant in
17 deciding whether a prospective customer can be trusted to deliver controlled substances only for
18 lawful purposes. This responsibility is critical, as . . . the illegal distribution of controlled substances
19 has a substantial and detrimental effect on the health and general welfare of the American people.”
20 The DEA’s September 27, 2006 letter also expressly reminded them that registrants, in addition to
21 reporting suspicious orders, have a “statutory responsibility to exercise due diligence to avoid filling
22 suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial
23 channels.” The same letter reminds distributors of the importance of their obligation to “be vigilant
24 in deciding whether a prospective customer can be trusted to deliver controlled substances only for
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1 lawful purposes,” and warns that “even just one distributor that uses its DEA registration to facilitate
2 diversion can cause enormous harm.”

3 603. The DEA sent another letter to Defendants on December 27, 2007, reminding them
4 that, as registered manufacturers and distributors of controlled substances, they share, and must each
5 abide by, statutory and regulatory duties to “maintain effective controls against diversion” and
6 ““design and operate a system to disclose to the registrant suspicious orders of controlled
7 substances.”” The DEA’s December 27, 2007 letter reiterated the obligation to detect, report, and
8 not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and
9 how to report (*e.g.*, by specifically identifying an order as suspicious, not merely transmitting data to
10 the DEA). Finally, the letter references the Revocation of Registration issued in *Southwood*
11 *Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487 (July 3, 2007), which discusses the obligation to report
12 suspicious orders and “some criteria to use when determining whether an order is suspicious.”
13
14

15 **b. Defendants Worked Together to Inflate the Quotas of**
16 **Opioids They Could Distribute**

17 604. Finding it impossible to legally achieve their ever-increasing sales ambitions,
18 Defendants engaged in the common purpose of increasing the supply of opioids and fraudulently
19 increasing the quotas that governed the manufacture and distribution of their prescription opioids.

20 605. Wholesale distributors such as the Distributor Defendants had close financial
21 relationships with both the Marketing Defendants and customers, for whom they provide a broad
22 range of value-added services that render them uniquely positioned to obtain information and control
23 against diversion. These services often otherwise would not be provided by manufacturers to their
24 dispensing customers and would be difficult and costly for the dispenser to reproduce. For example,
25 “[w]holesalers have sophisticated ordering systems that allow customers to electronically order and
26 confirm their purchases, as well as to confirm the availability and prices of wholesalers’ stock.”
27

28 *Fed. Trade Comm’n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998). Through their

1 generic source programs, wholesalers are also able “to combine the purchase volumes of customers
2 and negotiate the cost of goods with generic manufacturers.” *Id.* Wholesalers typically also offer
3 marketing programs, patient services, and other software to assist their dispensing customers.

4 606. The Distributor Defendants had financial incentives from the Marketing Defendants
5 to distribute higher volumes, and thus to refrain from reporting or declining to fill suspicious orders.
6 Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an
7 established wholesale acquisition cost. Discounts and rebates from this cost may be offered by
8 manufacturers based on market share and volume. As a result, higher volumes may decrease the
9 cost per pill to distributors. Decreased cost per pill, in turn, allows wholesale distributors to offer
10 more competitive prices, or alternatively, pocket the difference as additional profit. Either way, the
11 increased sales volumes result in increased profits.
12

13 607. The Marketing Defendants engaged in the practice of paying rebates and/or
14 chargebacks to the Distributor Defendants for sales of prescription opioids as a way to help them
15 boost sales and better target their marketing efforts. *The Washington Post* has described the practice
16 as industry-wide, and the HDA includes a “Contracts and Chargebacks Working Group,” suggesting
17 a standard practice. Further, in a recent settlement with the DEA, Mallinckrodt acknowledged that
18 “[a]s part of their business model Mallinckrodt collects transaction information, referred to as
19 chargeback data, from their direct customers (distributors). The transaction information contains
20 data relating to the direct customer sales of controlled substances to “downstream” registrants,
21 meaning pharmacies or other dispensaries, such as hospitals. The Marketing Defendants buy data
22 from pharmacies as well. This exchange of information, upon information and belief, would have
23 opened channels providing for the exchange of information revealing suspicious orders as well.
24

25 608. The contractual relationships among the Defendants also include vault security
26 programs. Defendants are required to maintain certain security protocols and storage facilities for
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28

1 the manufacture and distribution of their opioids. The manufacturers negotiated agreements
 2 whereby the Marketing Defendants installed security vaults for the Distributor Defendants in
 3 exchange for agreements to maintain minimum sales performance thresholds. These agreements
 4 were used by the Defendants as a tool to violate their reporting and diversion duties in order to reach
 5 the required sales requirements.

6
 7 609. In addition, Defendants worked together to achieve their common purpose through
 8 trade or other organizations, such as the Pain Care Forum (“PCF”) and the HDA.

9 610. The PCF has been described as a coalition of drug makers, trade groups and dozens of
 10 non-profit organizations supported by industry funding, including the Front Groups described in this
 11 complaint. The PCF recently became a national news story when it was discovered that lobbyists for
 12 members of the PCF quietly shaped federal and state policies regarding the use of prescription
 13 opioids for more than a decade.

14
 15 611. The Center for Public Integrity and The Associated Press obtained “internal
 16 documents shed[ding] new light on how drugmakers and their allies shaped the national response to
 17 the ongoing wave of prescription opioid abuse.”²¹⁰ Specifically, PCF members spent over \$740
 18 million lobbying in the nation’s capital and in all 50 statehouses on an array of issues, including
 19 opioid-related measures.²¹¹

20
 21 612. The Defendants who stood to profit from expanded prescription opioid use are
 22 members of and/or participants in the PCF.²¹² In 2012, membership and participating organizations

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 24 ²¹⁰ Matthew Perrone & Ben Wieder, *Pro-Painkiller Echo Chamber Shaped Policy Amid Drug*
 25 *Epidemic*, The Ctr. for Pub. Integrity (Sept. 19, 2016) (updated Dec. 15, 2016),
[https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-](https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic)
[amid-drug-epidemic](https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic).

26 ²¹¹ *Id.*

27 ²¹² *PAIN CARE FORUM 2012 Meetings Schedule* (last updated Dec. 2011),
 28 [https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-](https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf)
[amp.pdf](https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf).

1 included Endo, Purdue, Actavis and Cephalon.²¹³ Each of the Marketing Defendants worked
 2 together through the PCF. But the Marketing Defendants were not alone. The Distributor
 3 Defendants actively participated, and continue to participate, in the PCF, at a minimum, through
 4 their trade organization, the HDA.²¹⁴ The Distributor Defendants participated directly in the PCF as
 5 well.
 6

7 613. Additionally, the HDA led to the formation of interpersonal relationships and an
 8 organization among the Defendants. Although the entire HDA membership directory is private, the
 9 HDA website confirms that each of the Distributor Defendants and several of the Marketing
 10 Defendants, including Actavis, Endo, Purdue, Mallinckrodt, and Cephalon, were members of the
 11 HDA.²¹⁵ Additionally, the HDA and each of the Distributor Defendants, eagerly sought the active
 12 membership and participation of the Marketing Defendants by advocating for the many benefits of
 13 members, including “strengthen[ing] . . . alliances.”²¹⁶
 14

15 614. Beyond strengthening alliances, the benefits of HDA membership included the ability
 16 to, among other things, “network one on one with manufacturer executives at HDA’s members-only
 17 Business and Leadership Conference,” “networking with HDA wholesale distributor members,”
 18 “[o]pportunities to host and sponsor HDA Board of Directors events,” “participate on HDA
 19 committees, task forces and working groups with peers and trading partners,” and “make
 20

21
 22 ²¹³ Mallinckrodt became an active member of the PCF sometime after 2012.

23 ²¹⁴ *Id.* The Executive Committee of the HDA (formerly the HDMA) currently includes the chief
 24 executive officer, Pharmaceutical Segment, for Cardinal, the Executive Vice President and Group
 25 President for AmerisourceBergen, and the President, Pharmaceutical Solutions & Services for
 McKesson. *Executive Committee, Healthcare Distribution Alliance*,
<https://www.hda.org/about/executive-committee> (last visited Mar. 11, 2020).

26 ²¹⁵ *Manufacturer, Healthcare Distribution Alliance*, <https://www.hda.org/about/membership/manufacturer> (last visited Mar. 11, 2020).

27 ²¹⁶ *Manufacturer Membership, Healthcare Distribution Alliance*, <https://www.hda.org/~media/pdfs/membership/manufacturer-membership-benefits.ashx?la=en> (last visited Mar. 11, 2020).
 28

connections.”²¹⁷ Clearly, the HDA and the Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships and “alliances” between the Marketing and Distributor Defendants.

615. The application for manufacturer membership in the HDA further indicates the level of connection among the Defendants and the level of insight that they had into each other’s businesses.²¹⁸ For example, the manufacturer membership application must be signed by a “senior company executive,” and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company.

616. The HDA application also requests that the manufacturer identify its current distribution information, including the facility name and contact information. Manufacturer members were also asked to identify their “[m]ost [r]ecent [y]ear [e]nd [n]et [s]ales” through wholesale distributors, including Distributor Defendants AmerisourceBergen, Anda, Cardinal, McKesson and their subsidiaries.

617. The closed meetings of the HDA’s councils, committees, task forces and working groups provided the Marketing and Distributor Defendants with the opportunity to work closely together, confidentially, to develop and further the common purpose and interests of the enterprise.

618. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants advertise these conferences to the Marketing Defendants as an opportunity to “bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry

²¹⁷ *Id.*

²¹⁸ *Manufacturer Membership Application*, Healthcare Distribution Alliance, <https://www.hda.org/~media/pdfs/membership/manufacturer-membership-application.ashx?la=en> (last visited Mar. 11, 2020).

1 issues.”²¹⁹ The conferences also gave the Marketing and Distributor Defendants “unmatched
 2 opportunities to network with [their] peers and trading partners at all levels of the healthcare
 3 distribution industry.”²²⁰ The HDA and its conferences were significant opportunities for the
 4 Marketing and Distributor Defendants to interact at a high level of leadership. It is clear that the
 5 Marketing Defendants embraced this opportunity by attending and sponsoring these events.²²¹
 6

7 619. After becoming members of HDA, Defendants were eligible to participate on
 8 councils, committees, task forces and working groups, including:

9 (a) Industry Relations Council: “This council, composed of distributor and
 10 manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues.”

11 (b) Business Technology Committee: “This committee provides guidance to HDA
 12 and its members through the development of collaborative e-commerce business solutions. The
 13 committee’s major areas of focus within pharmaceutical distribution include information systems,
 14 operational integration and the impact of e-commerce.” Participation in this committee includes
 15 distributor and manufacturer members.
 16

17 (c) Logistics Operation Committee: “This committee initiates projects designed to
 18 help members enhance the productivity, efficiency and customer satisfaction within the healthcare
 19 supply chain. Its major areas of focus include process automation, information systems, operational
 20 integration, resource management and quality improvement.” Participation in this committee
 21 includes distributor and manufacturer members.
 22
 23

24 ²¹⁹ *2020 Business and Leadership Conference*, Healthcare Distribution Alliance,
 25 <https://www.hda.org/events/2020-business-and-leadership-conference> (last visited Mar. 11, 2020).

26 ²²⁰ *Id.*

27 ²²¹ *2015 Distribution Management Conference and Expo*, Healthcare Distribution Alliance,
 28 <https://web.archive.org/web/20160119143358/https://www.healthcaredistribution.org/events/2015-distribution-management-conference> (last visited Mar. 11, 2020).

1 (d) Manufacturer Government Affairs Advisory Committee: “This committee
2 provides a forum for briefing HDA’s manufacturer members on federal and state legislative and
3 regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such
4 issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of
5 distribution, importation and Medicaid/Medicare reimbursement.” Participation in this committee
6 includes manufacturer members.
7

8 (e) Contracts and Chargebacks Working Group: “This working group explores
9 how the contract administration process can be streamlined through process improvements or
10 technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and
11 chargeback professionals.” Participation in this group includes manufacturer and distributor
12 members.
13

14 620. The Distributor and Marketing Defendants also participated, through the HDA, in
15 Webinars and other meetings designed to exchange detailed information regarding their prescription
16 opioid sales, including purchase orders, acknowledgements, ship notices, and invoices. For
17 example, on April 27, 2011, the HDA offered a Webinar to “accurately and effectively exchange
18 business transactions . . . between distributors and manufacturers.” The Marketing Defendants used
19 this information to gather high-level data regarding overall distribution and direct the Distributor
20 Defendants on how to most effectively sell prescription opioids.
21

22 621. Taken together, the interaction and length of the relationships between and among the
23 Marketing and Distributor Defendants reflects a deep level of interaction and cooperation between
24 two groups in a tightly knit industry. The Marketing and Distributor Defendants were not two
25 separate groups operating in isolation or two groups forced to work together in a closed system.
26 Defendants operated together as a united entity, working together on multiple fronts, to engage in the
27 unlawful sale of prescription opioids.
28

1 622. The HDA and PCF are but two examples of the overlapping relationships and
2 concerted joint efforts to accomplish common goals that demonstrate the leaders of each of the
3 Defendants were in communication and cooperation.

4 623. Publications and guidelines issued by the HDA nevertheless confirm that the
5 Defendants utilized their membership in the HDA to form agreements. Specifically, in the fall of
6 2008, the HDA published the Industry Compliance Guidelines: Reporting Suspicious Orders and
7 Preventing Diversion of Controlled Substances (the “Industry Compliance Guidelines”) regarding
8 diversion. As the HDA explained in an amicus brief, the Industry Compliance Guidelines were the
9 result of “[a] committee of HDMA members contribut[ing] to the development of this publication”
10 beginning in late 2007.

11 624. This statement by the HDA and the Industry Compliance Guidelines support the
12 allegation that Defendants utilized the HDA to form agreements about their approach to their duties
13 under the CSA. As John M. Gray, President/CEO of the HDA stated to the Energy and Commerce
14 Subcommittee on Health in April 2014, is “difficult to find the right balance between proactive anti-
15 diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed
16 medications.” Here, it is apparent that all of the Defendants found the same balance – an
17 overwhelming pattern and practice of failing to identify, report or halt suspicious orders, and failure
18 to prevent diversion.

19 625. The Defendants’ scheme had a decision-making structure driven by the Marketing
20 Defendants and corroborated by the Distributor Defendants. The Marketing Defendants worked
21 together to control the state and federal governments’ response to the manufacture and distribution
22 of prescription opioids by increasing production quotas through a systematic refusal to maintain
23 effective controls against diversion and identify suspicious orders and report them to the DEA.
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1 632. Publicly available information confirms that Distributor and Marketing Defendants
2 funneled far more opioids into communities across the United States than could have been expected
3 to serve legitimate medical use and ignored other red flags of suspicious orders. This information,
4 along with the information known only to the Distributor and Marketing Defendants, would have
5 alerted them to potentially suspicious orders of opioids.

6 633. This information includes the following facts:

7 (a) distributors and manufacturers have access to detailed transaction-level data
8 on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and
9 pharmacy and includes the volume of opioids, dose, and the distribution of other controlled and non-
10 controlled substances;

11 (b) manufacturers make use of that data to target their marketing and, for that
12 purpose, regularly monitor the activity of doctors and pharmacies;

13 (c) manufacturers and distributors regularly visit pharmacies and doctors to
14 promote and provide their products and services, which allows them to observe red flags of
15 diversion;

16 (d) the Distributor Defendants together account for approximately 90% of all
17 revenues from prescription drug distribution in the United States, and each plays such a large part in
18 the distribution of opioids that its own volume provides a ready vehicle for measuring the overall
19 flow of opioids into a pharmacy or geographic area; and

20 (e) the Marketing Defendants purchased chargeback data (in return for discounts
21 to the Distributor Defendants) that allowed them to monitor the combined flow of opioids into a
22 pharmacy or geographic area.

23 634. The conclusion that Defendants were on notice of the problems of abuse and
24 diversion follows inescapably from the fact that they flooded communities with opioids in quantities
25

1 that they knew or should have known exceeded any legitimate market for opioids – even the wider
2 market for chronic pain.

3 635. At all relevant times, Defendants were in possession of national, regional, state, and
4 local prescriber- and patient-level data that allowed them to track prescribing patterns over time.
5 They obtained this information from data companies, including but not limited to: IMS Health,
6 QuintilesIMS, IQVIA, Pharmaceutical Data Services, Source Healthcare Analytics, NDS Health
7 Information Services, Verispan, Quintiles, SDI Health, ArcLight, Scriptline, Wolters Kluwer, and/or
8 PRA Health Science, and all of their predecessors or successors in interest (the “Data Vendors”).
9

10 636. The Distributor Defendants developed “know your customer” questionnaires and
11 files. This information, compiled pursuant to comments from the DEA in 2006 and 2007, was
12 intended to help Defendants identify suspicious orders or customers who were likely to divert
13 prescription opioids.²²² The “know your customer” questionnaires informed Defendants of the
14 number of pills that the pharmacies sold, how many non-controlled substances were sold compared
15 to controlled substances, whether the pharmacy buys from other distributors, the types of medical
16 providers in the area, including pain clinics, general practitioners, hospice facilities, and cancer
17 treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious
18 orders.
19

20 637. Defendants purchased nationwide, regional, state, and local prescriber- and patient-
21 level data from the Data Vendors that allowed them to track prescribing trends, identify suspicious
22 orders, identify patients who were doctor shopping, identify pill mills, etc. The Data Vendors’
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24
25 ²²² *Suggested Questions a Distributor should ask prior to shipping controlled substances*, Drug
26 Enf’t Admin., Diversion Control Div. (Apr. 12, 2011), [https://www.deadiversion.usdoj.gov/mtgs/](https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf)
27 [pharm_industry/14th_pharm/levinl_ques.pdf](https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf); Richard Widup, Jr., CPP & Kathleen H. Dooley, Esq.,
28 *Pharmaceutical Production Diversion: Beyond the PDMA*, Purdue Pharma and McGuireWoods
LLC (Oct. 2010), [https://www.mcguirewoods.com/news-resources/publications/lifesciences/](https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf)
[product_diversion_beyond_pdma.pdf](https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf).

1 information purchased by Defendants allowed them to view, analyze, compute, and track their
 2 competitors' sales, and to compare and analyze market share information.²²³

3 638. IMS Health, for example, provided Defendants with reports detailing prescriber
 4 behavior and the number of prescriptions written between competing products.

5 639. Similarly, Wolters Kluwer, an entity that eventually owned data mining companies
 6 that were created by McKesson (Source) and Cardinal (ArcLight), provided Defendants with charts
 7 analyzing the weekly prescribing patterns of multiple physicians, organized by territory, regarding
 8 competing drugs and analyzed the market share of those drugs.²²⁴

9 640. This information allowed Defendants to track and identify instances of
 10 overprescribing. In fact, one of the Data Vendors' experts testified that the Data Vendors'
 11 information could be used to track, identify, report and halt suspicious orders of controlled
 12 substances.²²⁵

13 641. Defendants were, therefore, collectively aware of the suspicious orders that flowed
 14 daily from their manufacturing and distribution facilities.

15 642. Defendants refused to identify, investigate and report suspicious orders to the DEA
 16 when they became aware of them, despite their actual knowledge of drug diversion rings. As
 17 described in detail below, Defendants refused to identify suspicious orders and diverted drugs
 18 despite the DEA issuing final decisions against distributors in 178 registrant actions between 2008
 19

20
 21
 22 ²²³ A Verispan representative testified that the Distributor Defendants use the prescribing
 23 information to "drive market share." Brief for Petitioners, *Sorrell v. IMS Health Inc.*, No. 10-779,
 2011 WL 661712, at *9-*10 (U.S. Feb. 22, 2011).

24 ²²⁴ Joint Appendix, Volume II, *Sorrell v. IMS Health Inc.*, No. 10-779, 2011 WL 705207, at *467-
 25 *471 (U.S. Feb. 22, 2011).

26 ²²⁵ In *Sorrell*, expert Eugene "Mick" Kolassa testified, on behalf of the Data Vendors, that "a firm
 27 that sells narcotic analgesics was able to use prescriber-identifiable information to identify
 28 physicians that seemed to be prescribing an inordinately high number of prescriptions for their
 product." Joint Appendix, Volume I, *Sorrell v. IMS Health Inc.*, No. 10-779, 2011 WL 687134, at
 *204 (U.S. Feb. 22, 2011).

1 and 2012 and 117 recommended decisions in registrant actions from the Office of Administrative
 2 Law Judges. These numbers include 76 actions involving orders to show cause and 41 actions
 3 involving immediate suspension orders, all for failure to report suspicious orders.

4 643. Sales representatives were also aware that the prescription opioids they were
 5 promoting were being diverted, often with lethal consequences. As a sales representative wrote on a
 6 public forum:
 7

8 Actions have consequences – so some patient gets Rx’d the 80mg OxyContin
 9 when they probably could have done okay on the 20mg (but their doctor got “sold”
 10 on the 80mg) and their teen son/daughter/child’s teen friend finds the pill bottle and
 11 takes out a few 80’s . . . next they’re at a pill party with other teens and some kid
 12 picks out a green pill from the bowl . . . they go to sleep and don’t wake up (because
 13 they don’t understand respiratory depression) Stupid decision for a teen to make . . .
 14 yes . . . but do they really deserve to die?

15 644. Moreover, Defendants’ sales incentives rewarded sales representatives who happened
 16 to have pill mills within their territories, enticing those representatives to look the other way even
 17 when their in-person visits to such clinics should have raised numerous red flags. In one example, a
 18 pain clinic in South Carolina was diverting massive quantities of OxyContin. People traveled to the
 19 clinic from towns as far as 100 miles away to get prescriptions. The DEA’s diversion unit raided the
 20 clinic, and prosecutors eventually filed criminal charges against the doctors. But Purdue’s sales
 21 representative for that territory, Eric Wilson, continued to promote OxyContin sales at the clinic. He
 22 reportedly told another local physician that this clinic accounted for 40% of the OxyContin sales in
 23 his territory. At that time, Wilson was Purdue’s top-ranked sales representative. In response to news
 24 stories about this clinic, Purdue issued a statement, declaring that ““if a doctor is intent on
 25 prescribing our medication inappropriately, such activity would continue regardless of whether we
 26 contacted the doctor or not.””²²⁶

27 ²²⁶ Barry Meier, *Pain Killer: A “Wonder” Drug’s Tale of Addiction and Death* 298-300 (Rodale
 28 2003).

645. In another example, a Purdue sales manager informed her supervisors in 2009 about a suspected pill mill in Los Angeles, reporting over email that, when she visited the clinic with her sales representative, “it was packed with a line out the door, with people who looked like gang members,” and that she felt “very certain that this an organized drug ring.”²²⁷ She wrote: “This is clearly diversion. Shouldn’t the DEA be contacted about this?” But her supervisor at Purdue responded that while they were “considering all angles,” it was “really up to [the wholesaler] to make the report.”²²⁸ This pill mill was the source of 1.1 million pills trafficked to Everett, Washington, a city of around 100,000 people. Purdue waited until after the clinic was shut down in 2010 to inform the authorities.

646. A Kadian prescriber guide discusses abuse potential of Kadian. It is full of disclaimers that Actavis has not done any studies on the topic and that the guide is “only intended to assist you in forming your own conclusion.” However, the guide includes the following statements: (1) the “unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users,” and (2) “KADIAN may be less likely to be abused by health care providers and illicit users” because of “Slow onset of action,” “Lower peak plasma morphine levels than equivalent doses of other formulations of morphine,” “Long duration of action,” and “Minimal fluctuations in peak to trough plasma levels of morphine at steady state.” The guide was copyrighted by Actavis in 2007, before Actavis officially purchased Kadian from Alpharma.

647. Defendants’ obligation to report suspicious prescribing ran head-on into their marketing strategy. Defendants did identify doctors who were their most prolific prescribers, not to

²²⁷ Harriet Ryan *et al.*, *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew*, Los Angeles Times (July 10, 2016), <http://www.latimes.com/projects/la-me-oxycotin-part2/>.

²²⁸ *Id.*

1 report them, but to market to them. It would make little sense to focus on marketing to doctors who
2 may be engaged in improper prescribing only to report them to law enforcement or to report those
3 doctors who drove Defendants' sales.

4 648. Defendants purchased data from IMS Health (now IQVIA) or other proprietary
5 sources to identify doctors to target for marketing and to monitor their own and competitors' sales.
6 Marketing visits were focused on increasing, sustaining, or converting the prescriptions of the
7 biggest prescribers, particularly through aggressive, high frequency detailing visits.

8 649. For example, at a national sales meeting presentation in 2011, Actavis pressed its
9 sales representatives to focus on its high prescribers: "To meet and exceed our quota, we must
10 continue to get Kadian scripts from our loyalists. MCOs will continue to manage the pain products
11 more closely. We MUST have new patient starts or we will fall back into 'the big leak.' We need to
12 fill the bucket faster than it leaks." "The selling message should reflect the opportunity and
13 prescribing preferences of each account. High Kadian Writers / Protect and Grow/ Grow = New
14 Patient Starts and Conversions." In an example of how new patients plus a high volume physician
15 can impact performance, the presentation stated: "102% of quota was achieved by just one high
16 volume physician initiating Kadian on 2-3 new patients per week."

17 650. The same is true for other Defendants. Teva directed its sales representatives to make
18 a "minimum of seven Fentora calls per day" and focus "on high prescribers to maintain and grow
19 their contribution." Another chart showed Cephalon ensured that the majority highest volume, or
20 "core prescribers," were detailed at least five times in ten months.

21 651. This focus on marketing to the highest prescribers had two impacts. First, it
22 demonstrates that manufacturers were keenly aware of the doctors who were writing large quantities
23 of opioid prescriptions. But instead of investigating or reporting those doctors, Defendants were
24 singularly focused on maintaining, capturing, or increasing their sales.

1 652. Whenever examples of opioid diversion and abuse have drawn media attention,
2 Purdue and other Marketing Defendants have consistently blamed “bad actors.” For example, in
3 2001, during a Congressional hearing, Purdue’s attorney Howard Udell answered pointed questions
4 about how it was that Purdue could utilize IMS Health data to assess their marketing efforts but not
5 notice a particularly egregious pill mill in Pennsylvania run by a doctor named Richard Paolino.
6 Udell asserted that Purdue was “fooled” by the doctor: “[T]he picture that is painted in the
7 newspaper [of Dr. Paolino] is of a horrible, bad actor, someone who preyed upon this community,
8 who caused untold suffering. And he fooled us all. He fooled law enforcement. He fooled the
9 DEA. He fooled local law enforcement. He fooled us.”

11 653. But given the closeness with which Defendants monitored prescribing patterns
12 through IMS Health data, it is highly improbable that they were “fooled.” In fact, a local pharmacist
13 had noticed the volume of prescriptions coming from Paolino’s clinic and alerted authorities. Purdue
14 had the prescribing data from the clinic and alerted no one. Indeed, a Purdue executive referred to
15 Purdue’s tracking system and database as a “gold mine” and acknowledged that Purdue could
16 identify highly suspicious volumes of prescriptions.

18 654. As discussed below, Endo knew that Opana ER was being widely abused. Yet the
19 New York Attorney General revealed, based on information obtained in an investigation into Endo,
20 that Endo sales representatives were not aware that they had a duty to report suspicious activity and
21 were not trained on the company’s policies or duties to report suspicious activity, and that Endo paid
22 bonuses to sales representatives for detailing prescribers who were subsequently arrested for illegal
23 prescribing.

25 655. Sales representatives making in-person visits to such clinics were likewise not fooled.
26 But as pill mills were lucrative for the manufacturers and individual sales representatives alike, the
27 Marketing Defendants and their employees turned a collective blind eye, allowing certain clinics to
28

1 dispense staggering quantities of potent opioids and feigning surprise when the most egregious
2 examples eventually made the nightly news.

3 **(2) Defendants Failed to Report Suspicious Orders**
4 **or Otherwise Act to Prevent Diversion**

5 656. As discussed above, Defendants failed to report suspicious orders, prevent diversion,
6 or otherwise control the supply of opioids flowing into communities across America, including San
7 Francisco. Despite the notice described above, and in disregard of their duties, Defendants
8 continued to pump massive quantities of opioids into communities despite their obligations to
9 control the supply, prevent diversion, and report and take steps to halt suspicious orders.

10 657. Government agencies and regulators have confirmed (and in some cases Defendants
11 have admitted) that Defendants did not meet their obligations and have uncovered especially blatant
12 wrongdoing.

13 658. For example, on January 5, 2017, McKesson entered into an Administrative
14 Memorandum Agreement with the DEA wherein it agreed to pay a \$150 million civil penalty for,
15 *inter alia*, failure to identify and report suspicious orders at its facilities in Aurora, CO; Aurora, IL;
16 Delran, NJ; LaCrosse, WI; Lakeland FL; Landover, MD; La Vista, NE; Livonia, MI; Methuen, MA;
17 Santa Fe Springs, CA; Washington Courthouse, OH; and West Sacramento, CA. McKesson
18 admitted that, at various times during the period from January 1, 2009 through the effective date of
19 the Agreement (January 17, 2017), it “did not identify or report to [the] DEA certain orders placed
20 by certain pharmacies which should have been detected by McKesson as suspicious based on the
21 guidance contained in the DEA Letters.”

22 659. McKesson further admitted that, during this time period, it “failed to maintain
23 effective controls against diversion of particular controlled substances into other than legitimate
24 medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA
25 and the CSA’s implementing regulations, 21 C.F.R. Part 1300 *et seq.*, at the McKesson Distribution
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Centers.” Due to these violations, McKesson agreed to a partial suspension of its authority to distribute controlled substances from certain of its facilities, some of which investigators found “were supplying pharmacies that sold to criminal drug rings.”

660. The wrongdoing identified in the Administrative Memorandum Agreement reached the top of the company. John Hammergren (“Hammergren”) was McKesson’s CEO from 2001 to 2019 and chairman of the board for all but the first year of that date range. Even before the time period covered by the Administrative Memorandum Agreement, Hammergren and the board were made aware that the people the company had directed to monitor sales of opioids were unaware of the need to do so. Hammergren took no action to address the risks arising from this lack of awareness.

661. Instead, McKesson’s response, under Hammergren’s leadership, was a continuous effort to evade regulatory oversight. He engaged in high level communications with White House advisors and made a personal lobbying trip to Washington, D.C., to avoid blame being appropriately placed on McKesson for its role in the opioid crisis. Compliance issues were rarely addressed at board meetings; when they were, the discussions were limited to approving the DEA settlements after longstanding failures had already occurred. Indeed, rather than addressing the need for compliance, Hammergren implemented employee scorecards that included customer satisfaction and profitability metrics, but not regulatory compliance.²²⁹

662. A special board committee would later acknowledge that McKesson’s senior management should have better informed the board of DEA concerns regarding its compliance.

663. Throughout this period, Hammergren was one of the highest paid CEOs in the United States, including ranking as the top-paid executive nationally in 2012. In 2017, notwithstanding

²²⁹ See *John H. Hammergren*, Reference for Business, <https://www.referenceforbusiness.com/biography/F-L/Hammergren-John-H-1959.html> (last visited Mar. 13, 2020) (scorecards tracked four metrics: customer satisfaction, employee satisfaction, process success (*i.e.*, efficiency), and financial success (*i.e.*, earnings)).

1 McKesson’s record \$150 million settlement with the DEA, Hammergren was awarded a \$1.1 million
 2 *increase* in his bonus pay.²³⁰ In all, he received more than \$360.8 million in compensation for
 3 running McKesson, \$692 million when factoring in the increase in McKesson’s stock value.²³¹

4 664. Similarly, in 2017, the DOJ fined Mallinckrodt \$35 million for its failure to report
 5 suspicious orders of controlled substances, including opioids, and for violating record-keeping
 6 requirements. The government alleged that “Mallinckrodt failed to design and implement an
 7 effective system to detect and report ‘suspicious orders’ for controlled substances – orders that are
 8 unusual in their frequency, size, or other patterns [and] Mallinckrodt supplied distributors, and the
 9 distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive
 10 quantity of oxycodone pills without notifying DEA of these suspicious orders.”

11 665. On December 23, 2016, Cardinal agreed to pay the United States \$44 million to
 12 resolve allegations that it violated the Controlled Substances Act in Maryland, Florida and New
 13 York by failing to report suspicious orders of controlled substances, including oxycodone, to the
 14 DEA. In the settlement agreement, Cardinal admitted, accepted, and acknowledged that it had
 15 violated the CSA between January 1, 2009 and May 14, 2012 by failing to:

16 (a) “timely identify suspicious orders of controlled substances and inform the
 17 DEA of those orders, as required by 21 C.F.R. §1301.74(b)”;

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 23 ²³⁰ Erika Fry, *Big McKesson Shareholder, Governance Experts Say the Opioid Crisis Should Have*
 24 *Cost the CEO Some Bonus Pay*, Fortune (July 10, 2017), [https://fortune.com/2017/07/10/mckesson-](https://fortune.com/2017/07/10/mckesson-ceo-pay-opioid-teamsters/)
 25 [ceo-pay-opioid-teamsters/](https://fortune.com/2017/07/10/mckesson-ceo-pay-opioid-teamsters/); see Bob Herman, *Health care CEOs took home \$2.6 billion in 2018*,
 26 *Axios* (May 16, 2019), [https://www.axios.com/health-care-ceo-pay-compensation-stock-2018-](https://www.axios.com/health-care-ceo-pay-compensation-stock-2018-0ed2a8aa-250e-48f1-a47a-849b8ca83e24.html)
 27 [0ed2a8aa-250e-48f1-a47a-849b8ca83e24.html](https://www.axios.com/health-care-ceo-pay-compensation-stock-2018-0ed2a8aa-250e-48f1-a47a-849b8ca83e24.html) (“Hammergren received a \$4 million bonus for
 28 hitting financial targets last year [2018], just as the company was facing a slew of lawsuits over its
 rule in the opioid crisis.”).

²³¹ Gary Rivlin, *He’s One of the Nation’s Highest-Paid CEOs – and You’ve Never Heard of Him*,
 Daily Beast (July 13, 2017), [https://www.thedailybeast.com/hes-one-of-the-nations-highest-paid-](https://www.thedailybeast.com/hes-one-of-the-nations-highest-paid-ceos-and-youve-never-heard-of-him)
[ceos-and-youve-never-heard-of-him](https://www.thedailybeast.com/hes-one-of-the-nations-highest-paid-ceos-and-youve-never-heard-of-him).

(b) “maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 C.F.R. §1301.74, including the failure to make records and reports required by the CSA or DEA’s regulations for which a penalty may be imposed under 21 U.S.C. §842(a)(5)”; and

(c) “execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA ‘Form 222’ order forms and their electronic equivalent for Schedule II controlled substances, as required by 21 U.S.C. §828 and 21 C.F.R. Part 1305.”

666. In 2012, the State of West Virginia filed a lawsuit against AmerisourceBergen and Cardinal, as well as several smaller wholesalers, alleging numerous causes of action, including violations of the CSA, consumer credit and protection and antitrust laws, and the creation of a public nuisance. Unsealed court records from that case demonstrate that AmerisourceBergen, along with McKesson and Cardinal, together shipped 423 million pain pills to West Virginia between 2007 and 2012. AmerisourceBergen itself shipped 80.3 million hydrocodone pills and 38.4 million oxycodone pills during that time period. These quantities alone are sufficient to show that the Defendants failed to control the supply chain or to report and take steps to halt suspicious orders. In 2016, AmerisourceBergen agreed to settle the West Virginia lawsuit for \$16 million to the state; Cardinal Health settled for \$20 million.

667. Thus, Defendants themselves have admitted that they, acting in disregard of their duties, pumped massive quantities of opioids into communities around the country, including San Francisco, despite their obligations to control the supply, prevent diversions, and report and take steps to halt suspicious orders.

3. Defendants Delayed a Response to the Opioid Crisis by Pretending to Cooperate with Law Enforcement

668. When a manufacturer or distributor does not report or stop suspicious orders, prescriptions for controlled substances may be written and dispensed to individuals who abuse them

1 or who sell them to others to abuse. This, in turn, fuels and expands the illegal market and results in
2 opioid-related overdoses. Without reporting by those involved in the supply chain, law enforcement
3 may be delayed in taking action – or may not know to take action at all.

4 669. After being caught failing to comply with particular obligations at particular facilities,
5 the Distributor Defendants made broad promises to change their ways and insisted that they sought
6 to be good corporate citizens. As part of McKesson’s 2008 settlement with the DEA, McKesson
7 claimed to have “taken steps to prevent such conduct from occurring in the future,” including
8 specific measures delineated in a “Compliance Addendum” to the settlement. Yet, in 2017,
9 McKesson paid \$150 million to resolve an investigation by the DOJ for again failing to report
10 suspicious orders of certain drugs, including opioids. Even though McKesson had been sanctioned
11 in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting
12 suspicious orders, and even though McKesson had specifically agreed in 2008 that it would no
13 longer violate those obligations, McKesson continued to violate the laws contrary to its written
14 agreement not to do so.
15

16
17 670. More generally, the Distributor Defendants publicly portrayed themselves as
18 committed to working with law enforcement, opioid manufacturers, and others to prevent diversion
19 of these dangerous drugs. For example, Cardinal claims that: “We challenge ourselves to best utilize
20 our assets, expertise and influence to make our communities stronger and our world more
21 sustainable, while governing our activities as a good corporate citizen and with a belief that doing
22 ‘the right thing’ serves everyone.” Defendant Cardinal likewise claims to “lead [its] industry in anti-
23 diversion strategies to help prevent opioids from being diverted for misuse or abuse.” Along the
24 same lines, it claims to “maintain a sophisticated, state-of-the-art program to identify, block and
25 report to regulators those orders of prescription controlled medications that do not meet [its] strict
26 criteria.” Defendant Cardinal also promotes funding it provides for “Generation Rx,” which funds
27
28

1 grants related to prescription drug misuse. A Cardinal executive recently claimed that Cardinal uses
 2 “advanced analytics” to monitor its supply chain; Cardinal assured the public it was being “as
 3 effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside
 4 criminal activity.”

5
 6 671. Along the same lines, McKesson publicly claims that its “customized analytics
 7 solutions track pharmaceutical product storage, handling and dispensing in real time at every step of
 8 the supply chain process,” creating the impression that McKesson uses this tracking to help prevent
 9 diversion. Defendant McKesson has also publicly stated that it has a “best-in-class controlled
 10 substance monitoring program to help identify suspicious orders,” and claimed it is “deeply
 11 passionate about curbing the opioid epidemic in our country.”

12
 13 672. Defendant AmerisourceBergen, too, has taken the public position that it is “work[ing]
 14 diligently to combat diversion and [is] working closely with regulatory agencies and other partners
 15 in pharmaceutical and healthcare delivery to help find solutions that will support appropriate access
 16 while limiting misuse of controlled substances.” A company spokeswoman also provided assurance
 17 that, “[a]t AmerisourceBergen, we are committed to the safe and efficient delivery of controlled
 18 substances to meet the medical needs of patients.”

19
 20 673. Moreover, in furtherance of their effort to affirmatively conceal their conduct and
 21 avoid detection, Defendants, through their trade associations, HDMA and the National Association
 22 of Chain Drug Stores (“NACDS”), filed an *amicus* brief in *Masters Pharmaceuticals*, which made
 23 the following statements:²³²

24
 25
 26
 27 ²³² Brief for HDMA and NACDS as Amici Curiae in Support of Neither Party, *Masters Pharms.,*
 28 *Inc. v. U.S. Drug Enf’t Admin.*, No. 15-1335, 2016 WL 1321983, at *3-*4, *25. (D.C. Cir. Apr. 4,
 2016).

1 (a) “HDMA and NACDS members not only have statutory and regulatory
2 responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts
3 as responsible members of society.”

4 (b) “Distributors take seriously their duty to report suspicious orders, utilizing
5 both computer algorithms and human review to detect suspicious orders based on the generalized
6 information that *is* available to them in the ordering process.”

7
8 674. Through the above statements made on their behalf by their trade associations, and
9 other similar statements assuring their continued compliance with their legal obligations, Defendants
10 not only acknowledged that they understood their obligations under the law, but they further
11 affirmed that their conduct was in compliance with those obligations.

12 675. Defendant Mallinckrodt similarly claims to be “committed . . . to fighting opioid
13 addiction and abuse,” and further asserts that: “In key areas, our initiatives go beyond what is
14 required by law. We address diversion and abuse through a multidimensional approach that includes
15 educational efforts, monitoring for suspicious orders of controlled substances”

16
17 676. Other Marketing Defendants also misrepresented their compliance with their legal
18 duties and their cooperation with law enforcement. Purdue serves as a hallmark example of such
19 wrongful conduct. Purdue deceptively and unfairly failed to report to authorities illicit or suspicious
20 prescribing of its opioids, even as it publicly and repeatedly touted its “constructive role in the fight
21 against opioid abuse,” including its commitment to ADF opioids and its “strong record of
22 coordination with law enforcement.”²³³

23
24
25 ²³³ Purdue, *Setting The Record Straight On OxyContin’s FDA-Approved Label* (May 5, 2016),
26 <https://web.archive.org/web/20170217222538/http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontin-fda-approved-label/> (last visited Mar. 12, 2020);
27 Purdue, *Setting The Record Straight On Our Anti-Diversion Programs*, (July 11, 2016)
28 <https://web.archive.org/web/20170120062853/http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/> (last visited Mar. 12, 2020).

1 677. At the heart of Purdue’s public outreach is the claim that it works hand in hand with
 2 law enforcement and government agencies to combat opioid abuse and diversion. Purdue has
 3 consistently trumpeted this partnership since at least 2008, and the message of close cooperation is in
 4 virtually all of Purdue’s recent pronouncements in response to the opioid abuse.

5 678. Touting the benefits of ADF opioids, Purdue’s website asserts: “[W]e are acutely
 6 aware of the public health risks these powerful medications create That’s why we work with
 7 health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid
 8 abuse and misuse”²³⁴ Purdue’s statement on “Opioids & Corporate Responsibility” likewise
 9 states that, “[f]or many years, Purdue has committed substantial resources to combat opioid abuse by
 10 partnering with . . . communities, law enforcement, and government.”²³⁵ And, responding to
 11 criticism of Purdue’s failure to report suspicious prescribing to government regulatory and
 12 enforcement authorities, the website similarly proclaims that Purdue “ha[s] a long record of close
 13 coordination with the DEA and other law enforcement stakeholders to detect and reduce drug
 14 diversion.”²³⁶

15 679. These public pronouncements create the misimpression that Purdue is proactively
 16 working with law enforcement and government authorities nationwide to root out drug diversion,
 17 including the illicit prescribing that can lead to diversion. It aims to distance Purdue from its past
 18
 19
 20
 21

22 ²³⁴ Purdue, *Opioids with Abuse-Deterrent Properties*, [http://www.purduepharma.com/healthcare-](http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/?cn-reloaded=1)
 23 [professionals/responsible-use-of-opioids/?cn-reloaded=1](http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/?cn-reloaded=1).

24 ²³⁵ Purdue, *Opioids Corporate Responsibility*, [https://web.archive.org/web/20170606131416/](https://web.archive.org/web/20170606131416/http://www.purduepharma.com/news-media/opioids-corporate-responsibility/)
 25 [https://web.archive.org/web/20170606131416/http://www.purduepharma.com/news-media/opioids-](https://web.archive.org/web/20170606131416/http://www.purduepharma.com/news-media/opioids-corporate-responsibility/)
[corporate-responsibility/](https://web.archive.org/web/20170606131416/http://www.purduepharma.com/news-media/opioids-corporate-responsibility/) (last visited Mar. 12, 2020).

26 ²³⁶ Purdue, *Setting The Record Straight On Our Anti-Diversion Programs* (July 11, 2016),
 27 [https://web.archive.org/web/20170120062853/http://www.purduepharma.com/news-media/get-the-](https://web.archive.org/web/20170120062853/http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/)
 28 [facts/setting-the-record-straight-on-our-anti-diversion-programs/](https://web.archive.org/web/20170120062853/http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/) (last visited Mar. 12, 2020).
 Contrary to its public statements, Purdue seems to have worked behind the scenes to push back
 against law enforcement.

1 conduct in deceptively marketing opioids and make its current marketing seem more trustworthy and
2 truthful.

3 680. Public statements by Defendants and their associates created the false and misleading
4 impression to regulators, prescribers, and the public that Defendants rigorously carried out their legal
5 duties, including their duty to report suspicious orders and exercise due diligence to prevent
6 diversion of these dangerous drugs, and further created the false impression that Defendants also
7 worked voluntarily to prevent diversion as a matter of corporate responsibility to the communities
8 their business practices would necessarily impact.

10 **F. The Opioids that Defendants Sold Migrated into Other Jurisdictions**

11 681. As the demand for prescription opioids grew, fueled by their potency and purity,
12 interstate commerce flourished: opioids moved from areas of high supply to areas of high demand,
13 traveling across state lines in a variety of ways.

14 682. First, prescriptions written in one state may, under some circumstances, be filled in a
15 different state. But even more significantly, individuals transported opioids from one jurisdiction
16 specifically to sell them in another.

17 683. When state authorities cracked down on opioid suppliers, out-of-state suppliers filled
18 the gaps. Florida in particular assumed a prominent role, as its lack of regulatory oversight created a
19 fertile ground for pill mills. Residents of other states would simply travel to Florida, stock up on
20 pills from a pill mill, and transport them back to home to sell. The practice became so common that
21 authorities dubbed these individuals “prescription tourists.”

22 684. Along the West Coast, over a million pills were transported from the Lake Medical
23 pain clinic in Los Angeles and cooperating pharmacies to the City of Everett, Washington. Couriers
24 drove up I-5 through California and Oregon, or flew from Los Angeles to Seattle. Moreover, opioids
25 were diverted to California from as far away as Maine. The I-95 corridor was a prominent transport
26
27
28

1 route for prescription pills. As the director of the Maine Drug Enforcement Agency explained, the
 2 oxycodone in Maine was coming up extensively from Florida, Georgia and California.

3 685. Abundant evidence, thus, establishes that prescription opioids migrated between
 4 cities, counties, and states, including into California. As a result, prescription data from any
 5 particular jurisdiction does not capture the full scope of the misuse, oversupply and diversion
 6 problem in that specific area. If prescription opioid pills were hard to get in one area, they migrated
 7 from another. The manufacturers and distributors were fully aware of this phenomenon and profited
 8 from it.

10 **G. The Devastating Effects of the Opioid Crisis Nationally**

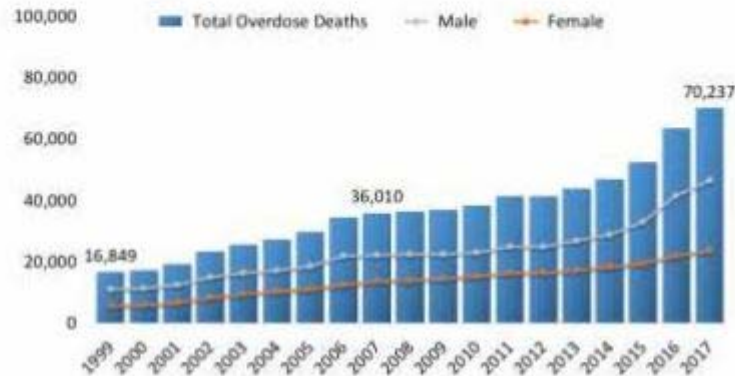
11 686. In 2014, more than 47,000 people died in the United States from lethal drug
 12 overdoses. In 2015, that number exceeded 52,000.²³⁷ In 2016, it exceeded 63,000 – more than the
 13 number of Americans who died during the entire Vietnam War, and more than the number of
 14 Americans who die from breast cancer every year.²³⁸ The number of overdose deaths in 2017 grew
 15 again, reaching more than 70,000, culminating in a two-fold increase in overdose mortality since
 16 2007.²³⁹

21 ²³⁷ *Overdose Death Rates*, National Institute on Drug Abuse, [https://www.drugabuse.gov/related-](https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates)
 22 [topics/trends-statistics/overdose-death-rates](https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates) (spreadsheet “Download Drug Overdoses data
 document,” data in “Number Drug OD Deaths” tab) (last visited Mar. 12, 2020).

23 ²³⁸ *Vietnam War U.S. Military Fatal Casualty Statistics*, National Archives,
 24 <https://www.archives.gov/research/military/vietnam-war/casualty-statistics> (last visited Mar. 13,
 2020); Rose A. Rudd et al., *Increases in Drug and Opioid Involved Overdose Deaths – United*
 25 *States, 2010-2015*, 65 *Morbidity & Mortality Weekly Report* 1445-52 (2016),
 26 <https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm>; Nadia Kounang, *Opioids now kill*
more people than breast cancer, CNN (Dec. 21, 2017), [https://www.cnn.com/2017/12/21/health/](https://www.cnn.com/2017/12/21/health/drug-overdoses-2016-final-numbers/index.html)
[drug-overdoses-2016-final-numbers/index.html](https://www.cnn.com/2017/12/21/health/drug-overdoses-2016-final-numbers/index.html).

27 ²³⁹ *Overdose Death Rates*, National Institute on Drug Abuse, [https://www.drugabuse.gov/related-](https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates)
 28 [topics/trends-statistics/overdose-death-rates](https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates) (last visited Mar. 12, 2020).

Figure 1. National Drug Overdose Deaths
Number Among All Ages, by Gender, 1999-2017



Source: Centers for Disease Control and Prevention, National Center for Health Statistics, Multiple Cause of Death, 1999-2017 on CDC WONDER Online Database, released December 2018

Figure 1. National Drug Overdose Deaths—Number Among All Ages, by Gender, 1999-2017. More than 70,200 Americans died from drug overdoses in 2017, including illicit drugs and prescription opioids—a 2-fold increase in a decade. The figure above is a bar and line graph showing the total number of U.S. overdose deaths involving all drugs from 1999 to 2017. Drug overdose deaths rose from 16,849 in 1999 to 70,237 in 2017. The bars are overlaid by lines showing the number of deaths by gender from 1999 to 2017 (Source: CDC WONDER).

687. More than three out of five of those overdose deaths involved opioids. In all, more than 217,000 people died in the United States between 1999 and 2017 from overdoses directly related to prescription opioids.²⁴⁰

688. That number does not account for the staggering number of additional illicit opioid deaths that relate back to the use of prescribed opioids. Four out of five new heroin users started with prescription opioid misuse.²⁴¹ It is thus unsurprising that heroin overdose deaths increased

²⁴⁰ See *Overdose Death Rates*, National Institute on Drug Abuse, <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates> (spreadsheet “Download Drug Overdoses data document,” data in “Number Drug OD Deaths” tab) (last visited Mar. 12, 2020).

²⁴¹ Christopher M. Jones, *Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers – United States, 2002-2004 and 2008-2010*, 132 (1-2) *Drug and Alcohol Dependence* 95-100 (Sept. 1, 2013), <http://www.drugandalcoholdependence.com/article/>

1 along with those attributed to prescription opioids; the CDC found a five-fold increase in the heroin
 2 death rate between 2002 and 2014.²⁴² Researchers also found that heroin use increased almost 140%
 3 among non-medical users of prescription opioids from the period 2002-2004 to the period 2011-
 4 2013.²⁴³ These changes appear to be driven primarily by market forces – “increased accessibility,
 5 reduced price, and high purity of heroin appear to be major drivers of the recent increases in rates of
 6 heroin use” – and predate recent policies aimed at combatting the abuse and diversion of prescription
 7 opioids.²⁴⁴

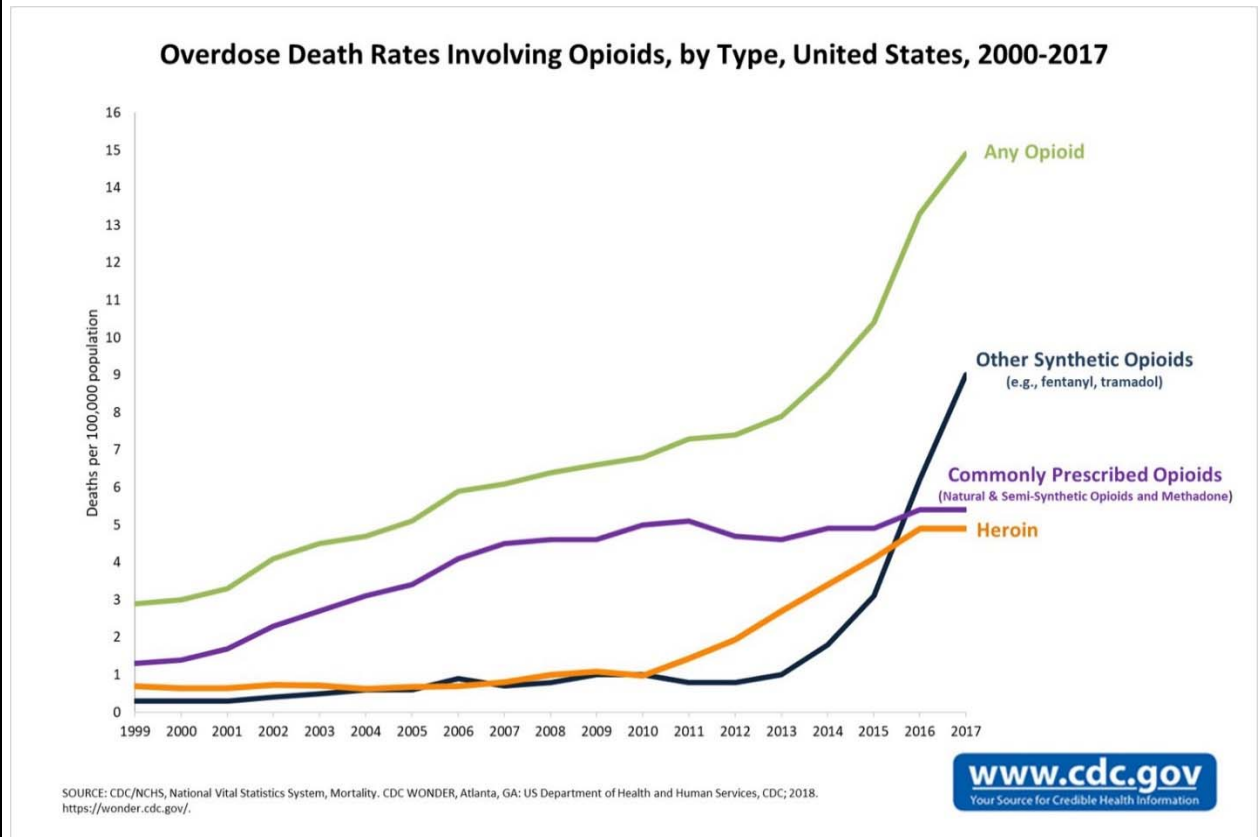
9 689. Further, according to Robert Anderson (“Anderson”), Chief of the Mortality Statistics
 10 Branch of the National Center for Health Statistics, there has been “more than an exponential
 11 increase” in overdose deaths from synthetic opioids such as fentanyl, which is reflected in the
 12 following graph from the CDC:
 13
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21 S0376-8716(13)00019-7/fulltext; Wilson M. Compton et al., *Relationship between Nonmedical*
 22 *Prescription-Opioid Use and Heroin Use*, 374 N. Eng. J. Med 154-63 (2016),
<https://www.nejm.org/doi/full/10.1056/NEJMr1508490>.

23 ²⁴² Centers for Disease Control and Prevention National Center for Health Statistics, *Number and*
 24 *age-adjusted rates of drug-poisoning deaths involving opioid analgesics and heroin: United States,*
 25 *1999-2014*, http://www.cdc.gov/nchs/data/health_policy/AADR_drug_poisoning_involving_OA_Heroin_US_2000-2014.pdf (last visited Mar. 13, 2020).

26 ²⁴³ Wilson M. Compton et al., *Relationship between Nonmedical Prescription-Opioid Use and*
 27 *Heroin Use*, 374 N. Eng. J. Med 154-63 (2016), <https://www.nejm.org/doi/full/10.1056/NEJMr1508490>.

28 ²⁴⁴ *Id.*



690. In all, more than 400,000 people died in the United States between 1999 and 2017 from opioid overdoses.²⁴⁵ A recent federally funded study, however, concluded that even this massive number understates the number of opioid overdose deaths. Indeed, the accurate number of opioid-related overdoses during the time period is likely 28% higher – approximately 500,000.²⁴⁶

691. This surge in opioid overdose deaths substantially contributed to a consecutive three-year decline in U.S. life expectancy, from 78.9 years in 2014, to 78.6 in 2017.²⁴⁷ And though life

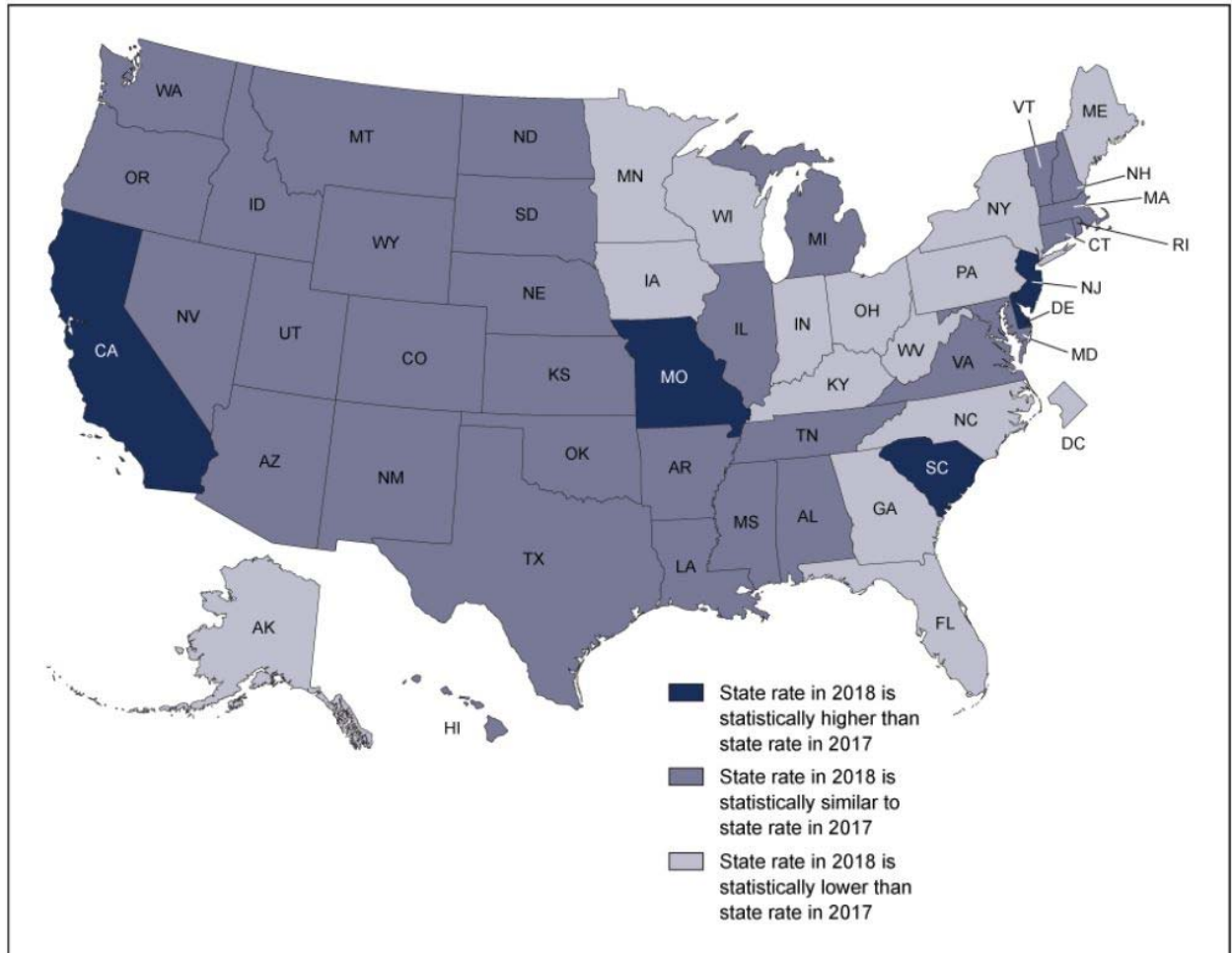
²⁴⁵ Steven Rich et al., *How the opioid epidemic evolved*, The Washington Post (Dec. 23, 2019), https://www.washingtonpost.com/graphics/2019/investigations/opioid-pills-overdose-analysis/?itid=lk_inline_manual_3.

²⁴⁶ Meryl Kornfield, *The death toll of the opioid epidemic is higher than originally thought, researchers say*, The Washington Post (Feb. 28, 2020), <https://www.washingtonpost.com/health/2020/02/28/opioid-deaths>.

²⁴⁷ Sabrina Tavernise & Abby Goodnough, *American Life Expectancy Rises for First Time in Four Years*, The New York Times (Jan. 30, 2020), <https://www.nytimes.com/2020/01/30/us/us-life-expectancy.html>.

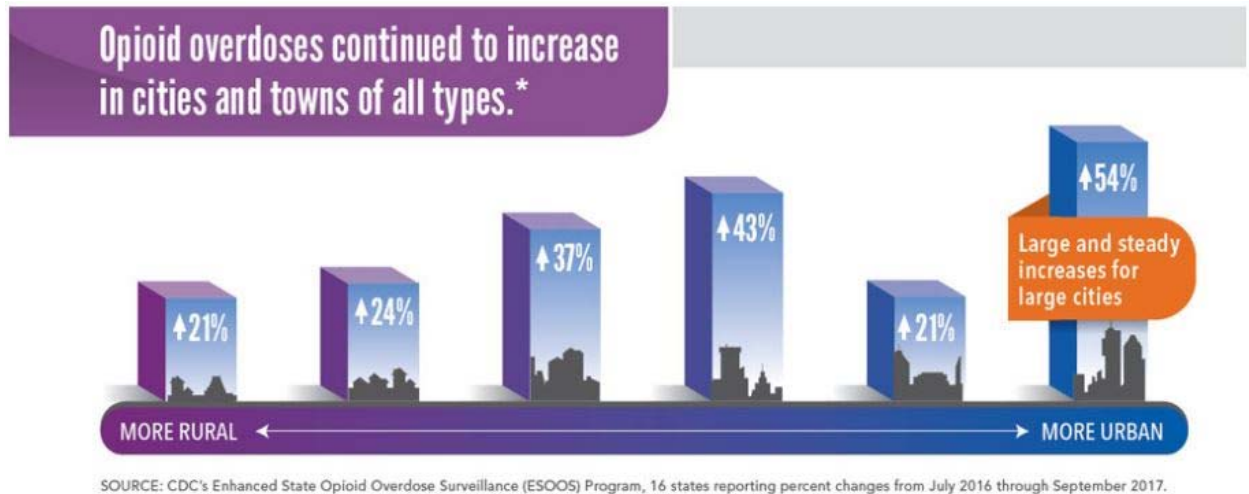
expectancy rose slightly in 2018 on a nationwide basis, California experienced a statistically significant increase in the rate of drug overdose deaths.²⁴⁸

Figure 2. Change in age-adjusted drug overdose death rates, by state: United States, 2017 and 2018



692. The toll of the opioid crisis cannot be measured solely by overdose deaths. According to a CDC report issued in March 2018, hospital emergency room visits for opioid overdoses rose 30% nationwide between July 2016 and September 2017, with overdoses increasing by 54% in large cities:

²⁴⁸ *Id.*; Holly Hedegaard et al., *Drug Overdose Deaths in the United States, 1999-2018*, CDC (Jan. 2020), <https://www.cdc.gov/nchs/products/databriefs/db356.htm>.



693. The economic impact of the opioid crisis is also staggering. According to an October 28, 2019 report issued by the White House, the country's opioid crisis is estimated to have cost \$696 billion in 2018 alone, and more than \$2.5 trillion for the four-year period from 2015 to 2018.²⁴⁹

694. Public health officials have called the current opioid epidemic the worst drug crisis in American history.²⁵⁰ According to Anderson, "I don't think we've ever seen anything like this. Certainly not in modern times."²⁵¹

695. On October 26, 2017, President Donald Trump declared the opioid epidemic a public health emergency. On February 27, 2018, then-Attorney General Jeff Sessions announced the creation of the DOJ's Prescription Interdiction & Litigation ("PIL") Task Force to fight the prescription opioid crisis.²⁵² "We have no time to waste," then-Attorney General Sessions

²⁴⁹ *The Full Cost of the Opioid Crisis: \$2.5 Trillion Over Four Years*, The White House (Oct. 28, 2019), <https://www.whitehouse.gov/articles/full-cost-opioid-crisis-2-5-trillion-four-years/>.

²⁵⁰ Julie Bosman, *Inside a Killer Drug Epidemic: A Look at America's Opioid Crisis*, The New York Times (Jan. 6, 2017), <https://www.nytimes.com/2017/01/06/us/opioid-crisis-epidemic.html>.

²⁵¹ *Drug overdoses now kill more Americans than guns*, CBS News (Dec. 9, 2016), <https://www.cbsnews.com/news/drug-overdose-deaths-heroin-opioid-prescription-painkillers-more-than-guns/>.

²⁵² Press Release, U.S. Department of Justice, *Attorney General Sessions Announces New Prescription Interdiction & Litigation Task Force* (Feb. 27, 2018), <https://www.justice.gov/opa/pr/attorney-general-sessions-announces-new-prescription-interdiction-litigation-task-force/>.

1 proclaimed. He continued: “Every day, 180 Americans die from drug overdoses. This epidemic
 2 actually lowered American life expectancy in 2015 and 2016 for the first time in decades, with drug
 3 overdose now the leading cause of death for Americans under age 50. These are not acceptable
 4 trends and this new task force will make us more effective in reversing them and saving Americans
 5 from the scourge of opioid addiction.”

6
 7 696. According to the press release accompanying its announcement, the PIL Task Force
 8 was established to, among other things, seek criminal and civil remedies to hold opioid
 9 manufacturers accountable for unlawful practices, and to ensure that distributors and pharmacies are
 10 obeying DEA rules designed to prevent diversion and improper prescribing. In addition, then-
 11 Attorney General Sessions directed the PIL Task Force to examine state and local government
 12 lawsuits against opioid manufacturers to determine what assistance federal law, and presumably
 13 federal agencies such as the DEA, can provide.
 14

15 **H. Defendants Conspired to Engage in the Wrongful Conduct**
 16 **Complained of Herein and Intended to Benefit Both Independently**
 17 **and Jointly from Their Conspiracy**

18 **1. Conspiracy Among the Marketing Defendants**

19 697. The Marketing Defendants agreed among themselves to set up, develop, and fund an
 20 unbranded promotion and marketing network to promote the use of opioids for the management of
 21 pain in order to mislead physicians, patients, health care providers, and health care payors through
 22 misrepresentations and omissions regarding the appropriate uses, risks, and safety of opioids, to
 23 increase sales, revenue, and profit from their opioid products.

24 698. This interconnected and interrelated network relied on the Marketing Defendants’
 25 collective use of unbranded marketing materials, such as KOLs, scientific literature, CMEs, patient
 26 education materials, and Front Groups developed and funded collectively by the Marketing
 27 Defendants, which were intended to mislead consumers and medical providers regarding the
 28 appropriate uses, risks, and safety of opioids.

1 699. The Marketing Defendants’ collective marketing scheme to increase opioid
2 prescriptions, sales, revenues and profits centered around the development, dissemination, and
3 reinforcement of nine false propositions: (1) that addiction is rare among patients taking opioids for
4 pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by
5 opioid patients are actually symptoms of an invented condition dubbed “pseudoaddiction”; (4) that
6 withdrawal is easily managed; (5) that increased dosing presents no significant risks; (6) that long-
7 term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are
8 greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction;
9 and (9) that abuse-deterrent formulations provide a solution to opioid abuse.

11 700. The Marketing Defendants knew that none of these propositions was true and that
12 there was no evidence to support them.

14 701. Each Marketing Defendant worked individually and collectively to develop and
15 actively promulgate these nine false propositions in order to mislead physicians, patients, health care
16 providers, and healthcare payors regarding the appropriate uses, risks, and safety of opioids.

17 702. What is particularly remarkable about the Marketing Defendants’ effort is the
18 seamless method in which the Marketing Defendants joined forces to achieve their collective goal: to
19 persuade consumers and medical providers of the safety of opioids and to hide their actual risks and
20 dangers. In doing so, the Marketing Defendants effectively built a new – and extremely lucrative –
21 opioid marketplace for their select group of industry players.

23 703. The Marketing Defendants’ unbranded promotion and marketing network was a
24 wildly successful marketing tool that achieved marketing goals that would have been impossible to
25 have been met by a single or even a handful of the network’s distinct corporate members.

26 704. For example, the network members pooled their vast marketing funds and dedicated
27 them to expansive and normally cost-prohibitive marketing ventures, such as the creation of Front
28

1 Groups. These collaborative networking tactics allowed each of the Marketing Defendants to
2 diversify its marketing efforts, all the while sharing any risk and exposure, financial and/or legal,
3 with other Marketing Defendants.

4 705. The most unnerving tactic utilized by the Marketing Defendants' network was their
5 unabashed mimicry of the scientific method of citing "references" in their materials. In the scientific
6 community, cited materials and references are rigorously vetted by objective unbiased and
7 disinterested experts in the field, and an unfounded theory or proposition would, or should, never
8 gain traction.

10 706. The Marketing Defendants put their own twist on the scientific method: they worked
11 together to manufacture wide support for their unfounded theories and propositions involving
12 opioids. Due to their sheer numbers and resources, the Marketing Defendants were able to create a
13 false consensus through their materials and references.

15 707. An illustrative example of the Marketing Defendants' utilization of this tactic is the
16 wide promulgation of the Porter & Jick Letter, which declared the incidence of addiction "rare" for
17 patients treated with opioids. The authors had analyzed a database of hospitalized patients who were
18 given opioids in a controlled setting to ease suffering from acute pain. These patients were *not* given
19 long-term opioid prescriptions or provided opioids to administer to themselves at home, nor was it
20 known how frequently or infrequently and in what doses the patients were given their narcotics.
21 Rather, it appears the patients were treated with opioids for short periods of time under in-hospital
22 doctor supervision.

24 708. Nonetheless, the Marketing Defendants widely and repeatedly cited this letter as
25 proof of a low addiction risk in connection with taking opioids, despite its obvious shortcomings.
26 The Marketing Defendants' egregious misrepresentations based on this letter included claims that
27 less than one percent of opioid users became addicted.

1 709. The Marketing Defendants’ collective misuse of the Porter & Jick Letter helped the
 2 opioid manufacturers convince patients and healthcare providers that opioids were not a concern.
 3 The enormous impact of the Marketing Defendants’ misleading amplification of this letter was well
 4 documented in another letter published in the *NEJM* on June, 1, 2017, describing the way the one-
 5 paragraph 1980 letter had been irresponsibly cited and in some cases “grossly misrepresented.” In
 6 particularly, the authors of this letter explained:
 7

8 [W]e found that a five-sentence letter published in the Journal in 1980 was heavily
 9 and uncritically cited as evidence that addiction was rare with long-term opioid
 10 therapy. We believe that this citation pattern contributed to the North American
 11 opioid crisis by helping to shape a narrative that allayed prescribers’ concerns about
 12 the risk of addiction associated with long-term opioid therapy.

11 710. By knowingly misrepresenting the appropriate uses, risks, and safety of opioids, the
 12 Marketing Defendants committed overt acts in furtherance of their conspiracy.

13 **2. Conspiracy Among All Defendants**

14 711. In addition, and on an even broader level, all Defendants took advantage of the
 15 industry structure, including end-running its internal checks and balances, to their collective
 16 advantage. Defendants agreed among themselves to increasing the supply of opioids and
 17 fraudulently increasing the quotas that governed the manufacture and supply of prescription opioids.
 18 Defendants did so to increase sales, revenue, and profit from their opioid products.
 19

20 712. The interaction and length of the relationships between and among the Defendants
 21 reflects a deep level of interaction and cooperation between Defendants in a tightly knit industry.
 22 The Marketing and Distributor Defendants were not two separate groups operating in isolation or
 23 two groups forced to work together in a closed system. The Defendants operated together as a
 24 united entity, working together on multiple fronts, to engage in the unlawful sale of prescription
 25 opioids.
 26
 27
 28

1 713. Defendants collaborated to expand the opioid market in an interconnected and
2 interrelated network in the following ways, as set forth more fully below, including, for example,
3 membership in the HDA.

4 714. Defendants utilized their membership in the HDA and other forms of collaboration to
5 form agreements about their approach to their duties under the CSA to report suspicious orders.
6 Defendants overwhelmingly agreed on the same approach – to fail to identify, report or halt
7 suspicious opioid orders, and fail to prevent diversion. Defendants’ agreement to restrict reporting
8 provided an added layer of insulation from DEA scrutiny for the entire industry, as Defendants were
9 thus collectively responsible for each other’s compliance with their reporting obligations.
10 Defendants were aware, both individually and collectively, of the suspicious orders that flowed
11 directly from Defendants’ facilities.
12

13 715. Defendants knew that their own conduct could be reported by other Defendants and
14 that their failure to report suspicious orders they filled could be brought to the DEA’s attention. As a
15 result, Defendants had an incentive to communicate with each other about the reporting or suspicious
16 orders to ensure consistency in their dealings with the DEA.
17

18 716. Defendants also worked together to ensure that the opioid quotas allowed by the DEA
19 remained artificially high and ensured that suspicious orders were not reported to the DEA in order
20 to ensure that the DEA had no basis for refusing to increase or decrease production quotas due to
21 diversion.
22

23 717. The desired consistency and collective end goal was achieved. Defendants achieved
24 blockbuster profits through higher opioid sales by orchestrating the unimpeded flow of opioids.
25
26
27
28

I. Statutes of Limitations Are Tolled and Defendants Are Estopped from Asserting Statutes of Limitations as Defenses

1. Continuing Conduct

718. Plaintiffs contend they continue to suffer harm from the unlawful actions by Defendants.

719. The continued tortious and unlawful conduct by Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The public nuisance remains unabated. The conduct causing the damages remains unabated.

2. Equitable Estoppel and Fraudulent Concealment

720. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook active efforts to deceive Plaintiffs and to purposefully conceal their unlawful conduct and fraudulently assure Plaintiffs and the public at large that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status in the State of California and to continue generating profits. Notwithstanding the allegations set forth above, Defendants have affirmatively assured Plaintiffs and the public at large that they are working to curb the opioid epidemic.

721. Defendants were deliberate in taking steps to conceal their conspiratorial behavior and active role in the deceptive marketing and the oversupply of opioids through overprescribing and suspicious sales, all of which fueled the opioid epidemic.

722. As set forth herein, the Marketing Defendants deliberately worked through Front Groups purporting to be patient advocacy and professional organizations, through public relations companies hired to work with the Front Groups and through paid KOLs to secretly control

1 messaging, influence prescribing practices and drive sales. The Marketing Defendants concealed
2 their role in shaping, editing, and approving the content of prescribing guidelines, informational
3 brochures, KOL presentations and other false and misleading materials addressing pain management
4 and opioids that were widely disseminated to regulators, prescribers and the public at large. They
5 concealed the addictive nature and dangers associated with opioid use and denied blame for the
6 epidemic attributing it instead solely to abuse and inappropriate prescribing. They manipulated
7 scientific literature and promotional materials to make it appear that misleading statements about the
8 risks, safety, and superiority of opioids were actually accurate, truthful, and supported by substantial
9 scientific evidence. Through their public statements, omissions, marketing, and advertising, the
10 Marketing Defendants' deceptions deprived Plaintiffs of actual or implied knowledge of facts
11 sufficient to put Plaintiffs on notice of potential claims.
12

13
14 723. Defendants also concealed from Plaintiffs the existence of Plaintiffs' claims by hiding
15 their lack of cooperation with law enforcement and affirmatively seeking to convince the public that
16 their legal duties to report suspicious sales had been satisfied through public assurances that they
17 were working to curb the opioid epidemic. They publicly portrayed themselves as committed to
18 working diligently with law enforcement and others to prevent diversion of these dangerous drugs
19 and curb the opioid epidemic, and they made broad promises to change their ways, insisting they
20 were good corporate citizens. These repeated misrepresentations misled regulators, prescribers and
21 the public, including Plaintiffs, and deprived Plaintiffs of actual or implied knowledge of facts
22 sufficient to put Plaintiffs on notice of potential claims.
23

24 724. Plaintiffs did not discover the nature, scope and magnitude of Defendants'
25 misconduct, and its full impact on Plaintiffs, and could not have acquired such knowledge earlier
26 through the exercise of reasonable diligence.
27
28

1 725. The Marketing Defendants’ campaign to misrepresent and conceal the truth about the
 2 opioid drugs that they were aggressively pushing in San Francisco deceived the medical community,
 3 consumers, and Plaintiffs.

4 726. Further, Defendants have also concealed and prevented discovery of information,
 5 including data from the ARCOS database, that will confirm their identities and the extent of their
 6 wrongful and illegal activities. On April 11, 2018, the Northern District of Ohio ordered the
 7 transactional ARCOS data be produced, over Defendants’ strenuous objections. In so doing, the
 8 court reviewed its previous decisions on this data and held that, because the transactional data had
 9 not yet been produced, Plaintiffs *could not identify* the potential defendants in this litigation, and
 10 further held that such information was “critical”:
 11

12 This means Plaintiffs still do not know: (a) which manufacturers (b) sold what types
 13 of pills (c) to which distributors; nor do they know (d) which distributors (e) sold
 14 what types of pills (f) to which retailers (g) in what locations. In any given case,
 15 therefore, the Plaintiff[s] still cannot know for sure who are the correct defendants, or
 16 the scope of their potential liability. . . .

17 [The] DEA and [the] defendants . . . [have] conceded the data was relevant and
 18 necessary to litigation. . . .

19 . . . Discovery of precisely which manufacturers sent which drugs to which
 20 distributors, and which distributors sent which drugs to which pharmacies and
 21 doctors, is critical not only to all of plaintiffs’ claims, but also to the Court’s
 22 understanding of the width and depth of this litigation.

23 *In re: Nat. Prescription Opiate Litig.*, No. 1:17-MD-2804, Order Regarding ARCOS Data at 6-8
 24 (N.D. Ohio Apr. 11, 2018) (ECF No. 233) at 6-8.

25 727. Defendants intended that their actions and omissions would be relied upon, including
 26 by Plaintiffs and the public at large. Plaintiffs and the public at large did not know and did not have
 27 the means to know the truth, due to Defendants’ actions and omissions.

28 728. Plaintiffs and the public at large reasonably relied on Defendants’ affirmative
 statements regarding their purported compliance with their obligations under the law and consent
 orders.

J. Facts Illustrating the Egregiousness of Defendants' Conduct

729. As set forth above, Defendants acted deliberately to increase sales of, and profits from, opioid drugs. The Marketing Defendants knew there was no support for their claims that addiction was rare, that addiction risk could be effectively managed, that signs of addiction were merely “pseudoaddiction,” that withdrawal is easily managed, that higher doses pose no significant additional risks, that long-term use of opioids improves function, or that time-release or abuse-deterrent formulations would prevent addiction or abuse. Nonetheless, they knowingly promoted these falsehoods in order to increase the market for their addictive drugs.

730. All of the Defendants, moreover, knew that large and suspicious quantities of opioids were being poured into communities throughout the United States, yet, despite this knowledge, they took no steps to report suspicious orders, control the supply of opioids, or otherwise prevent diversion. Indeed, as described above, Defendants acted in concert together to maintain high levels of quotas for their products and to ensure that suspicious orders would not be reported to regulators.

731. Defendants' conduct was so willful and deliberate that it continued in the face of numerous enforcement actions, fines, and other warnings from state and local governments and regulatory agencies. Defendants paid their fines, made promises to do better, and continued on with their marketing and supply schemes. This ongoing course of conduct knowingly, deliberately and repeatedly threatened and accomplished harm and risk of harm to public health and safety, and large scale economic loss to communities and government liabilities across the country.

732. Defendants' actions demonstrated both malice and also aggravated and egregious fraud. Defendants engaged in the conduct alleged herein with a conscious disregard for the rights and safety of other persons, even though that conduct had a great probability of causing substantial harm. The Marketing Defendants' fraudulent wrongdoing was done with a particularly gross and conscious disregard.

1 **1. The Marketing Defendants Persisted in Their Fraudulent**
 2 **Scheme Despite Repeated Admonitions, Warnings, and Even**
 3 **Prosecutions**

4 733. So determined were the Marketing Defendants to sell more opioids that they simply
 5 ignored multiple admonitions, warnings and prosecutions. These governmental and regulatory
 6 actions included:

7 **a. FDA Warnings to Janssen Failed to Deter Janssen's**
 8 **Misleading Promotion of Duragesic**

9 734. On February 15, 2000, the FDA sent Janssen a letter concerning the dissemination of
 10 “homemade” promotional pieces that promoted the Janssen drug Duragesic in violation of the
 11 Federal Food, Drug, and Cosmetic Act. In a subsequent letter, dated March 30, 2000, the FDA
 12 explained that the “homemade” promotional pieces were “false or misleading because they contain
 13 misrepresentations of safety information, broaden Duragesic’s indication, contain unsubstantiated
 14 claims, and lack fair balance.” The March 30, 2000 letter detailed numerous ways in which
 15 Janssen’s marketing was misleading.

16 735. The letter did not stop Janssen. On September 2, 2004, the U.S. Department of
 17 Health and Human Services (“HHS”) sent Janssen a warning letter concerning Duragesic due to
 18 “false or misleading claims about the abuse potential and other risks of the drug, and . . .
 19 unsubstantiated effectiveness claims for Duragesic,” including, specifically, “suggesting that
 20 Duragesic has a lower potential for abuse compared to other opioid products.” The September 2,
 21 2004 letter detailed a series of unsubstantiated, false, or misleading claims.

22 736. One year later, Janssen was still at it. On July 15, 2005, the FDA issued a public
 23 health advisory warning doctors of deaths resulting from the use of Duragesic and its generic
 24 competitor, manufactured by Mylan N.V. The advisory noted that the FDA had been ““examining
 25 the circumstances of product use to determine if the reported adverse events may be related to
 26 inappropriate use of the patch”” and noted the possibility “that patients and physicians might be
 27
 28

unaware of the risks” of using the fentanyl transdermal patch, which is a potent opioid analgesic approved only for chronic pain in opioid-tolerant patients that could not be treated by other drugs.

b. Governmental Action, Including Large Monetary Fines, Failed to Stop Cephalon from Falsely Marketing Actiq for Off-Label Uses

737. On September 29, 2008, Cephalon finalized and entered into a corporate integrity agreement with the Office of the Inspector General of HHS and agreed to pay \$425 million in civil and criminal penalties for its off-label marketing of Actiq and two other drugs (Gabitril and Provigil). According to a DOJ press release, Cephalon had trained sales representatives to disregard restrictions of the FDA-approved label, employed sales representatives and healthcare professionals to speak to physicians about off-label uses of the three drugs and funded CMEs to promote off-label uses.

738. Notwithstanding letters, an FDA safety alert, DOJ and state investigations, and the massive settlement, Cephalon has continued its deceptive marketing strategy.

c. FDA Warnings Did Not Prevent Cephalon from Continuing False and Off-Label Marketing of Fentora

739. On September 27, 2007, the FDA issued a public health advisory to address numerous reports that patients who did not have cancer or were not opioid tolerant had been prescribed Fentora, and death or life-threatening side effects had resulted. The FDA warned: “Fentora should not be used to treat any type of short-term pain.” Indeed, FDA specifically denied Cephalon’s application, in 2008, to broaden the indication of Fentora to include treatment of non-cancer breakthrough pain and use in patients who were not already opioid-tolerant.

740. Flagrantly disregarding the FDA’s refusal to broaden the indication for Fentora, Cephalon nonetheless marketed Fentora beyond its approved indications. On March 26, 2009, the FDA warned Cephalon against its misleading advertising of Fentora (the “Warning Letter”). The Warning Letter described a Fentora Internet advertisement as misleading because it purported to

1 broaden “the indication for Fentora by implying that any patient with cancer who requires treatment
 2 for breakthrough pain is a candidate for Fentora . . . when this is not the case.” It further criticized
 3 Cephalon’s other direct Fentora advertisements because they did not disclose the risks associated
 4 with the drug.

5
 6 741. Despite this warning, Cephalon continued to use the same sales tactics to push
 7 Fentora as it did with Actiq. For example, on January 13, 2012, Cephalon published an insert in
 8 *Pharmacy Times* titled *An Integrated Risk Evaluation and Mitigation Strategy (REMS) for*
 9 *FENTORA (Fentanyl Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate)*. Despite the
 10 repeated warnings of the dangers associated with the use of the drugs beyond their limited
 11 indication, as detailed above, the first sentence of the insert states: “It is well recognized that the
 12 judicious use of opioids can facilitate effective and safe management of chronic pain.”

13
 14 **d. A Guilty Plea and a Large Fine Did Not Deter Purdue**
 15 **from Continuing Its Fraudulent Marketing of**
OxyContin

16 742. In May 2007, Purdue and three of its executives pled guilty to federal charges of
 17 misbranding OxyContin in what the company acknowledged was an attempt to mislead doctors
 18 about the risk of addiction. Purdue was ordered to pay \$600 million in fines and fees. In its plea,
 19 Purdue admitted that its promotion of OxyContin was misleading and inaccurate, misrepresented the
 20 risk of addiction and was unsupported by science. Additionally, Michael Friedman, the company’s
 21 president, pled guilty to a misbranding charge and agreed to pay \$19 million in fines; Howard R.
 22 Udell, Purdue’s top lawyer, also pled guilty and agreed to pay \$8 million in fines; and Paul D.
 23 Goldenheim, its former medical director, pled guilty as well and agreed to pay \$7.5 million in fines.

24
 25 743. Nevertheless, even after the settlement, Purdue continued to pay doctors on speakers’
 26 bureaus to promote the liberal prescribing of OxyContin for chronic pain and fund seemingly neutral
 27 organizations to disseminate the message that opioids were non-addictive as well as other
 28

misrepresentations. At least until early 2018, Purdue continued to deceptively market the benefits of opioids for chronic pain while diminishing the associated dangers of addiction. After Purdue made its guilty plea in 2007, it assembled an army of lobbyists to fight any legislative actions that might encroach on its business. Between 2006 and 2015, Purdue and other painkiller producers, along with their associated nonprofits, spent nearly \$900 million dollars on lobbying and political contributions – eight times what the gun lobby spent during that period.

2. Repeated Admonishments and Fines Did Not Stop Defendants from Ignoring Their Obligations to Control the Supply Chain and Prevent Diversion

744. Defendants were repeatedly admonished and even fined by regulatory authorities, but continued to disregard their obligations to control the supply chain of dangerous opioids and to institute controls to prevent diversion.

745. In a *60 Minutes* interview last fall, former DEA agent Joe Rannazzisi described Defendants' industry as "out of control," stating that "[w]hat they wanna do, is do what they wanna do, and not worry about what the law is. And if they don't follow the law in drug supply, people die. That's just it. People die." He further explained that:

JOE RANNAZZISI: The three largest distributors are Cardinal Health, McKesson, and AmerisourceBergen. They control probably 85 or 90 percent of the drugs going downstream.

[INTERVIEWER]: You know the implication of what you're saying, that these big companies knew that they were pumping drugs into American communities that were killing people.

JOE RANNAZZISI: That's not an implication, that's a fact. That's exactly what they did.

746. Another DEA veteran similarly stated that these companies failed to make even a "good faith effort" to "do the right thing." He further explained that "I can tell you with 100 percent accuracy that we were in there on multiple occasions trying to get them to change their behavior. And they just flat out ignored us."

1 747. Government actions against the Defendants with respect to their obligations to control
2 the supply chain and prevent diversion include:

3 (a) On April 24, 2007, the DEA issued an Order to Show Cause and Immediate
4 Suspension Order against the AmerisourceBergen Orlando, Florida distribution center alleging
5 failure to maintain effective controls against diversion of controlled substances. On June 22, 2007,
6 AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

7 (b) On November 28, 2007, the DEA issued an Order to Show Cause and
8 Immediate Suspension Order against the Cardinal Auburn, Washington Distribution Center
9 (“Auburn Facility”) for failure to maintain effective controls against diversion of hydrocodone;

10 (c) On December 5, 2007, the DEA issued an Order to Show Cause and
11 Immediate Suspension Order against the Cardinal Lakeland, Florida Distribution Center (“Lakeland
12 Facility”) for failure to maintain effective controls against diversion of hydrocodone;
13

14 (d) On December 7, 2007, the DEA issued an Order to Show Cause and
15 Immediate Suspension Order against the Cardinal Swedesboro, New Jersey Distribution Center
16 (“Swedesboro Facility”) for failure to maintain effective controls against diversion of hydrocodone;

17 (e) On January 30, 2008, the DEA issued an Order to Show Cause against the
18 Cardinal Stafford, Texas Distribution Center (“Stafford Facility”) for failure to maintain effective
19 controls against diversion of hydrocodone;
20

21 (f) On September 30, 2008, Cardinal entered into a Settlement and Release
22 Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn,
23 Lakeland, Swedesboro and Stafford Facilities. The document also referenced allegations by the
24 DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances
25 at its distribution facilities located in McDonough, Georgia (“McDonough Facility”), Valencia,
26 California (“Valencia Facility”) and Denver, Colorado (“Denver Facility”);
27
28

1 (g) On February 2, 2012, the DEA issued an Order to Show Cause and Immediate
2 Suspension Order against the Cardinal Lakeland Facility for failure to maintain effective controls
3 against diversion of oxycodone; and

4 (h) On December 23, 2016, Cardinal agreed to pay a \$44 million fine to the DEA
5 to resolve the civil penalty portion of the administrative action taken against its Lakeland Facility.
6

7 748. McKesson's conscious and deliberate disregard of its obligations was especially
8 flagrant. On May 2, 2008, McKesson entered into an Administrative Memorandum of Agreement
9 ("2008 McKesson MOA") with the DEA that provided McKesson would "maintain a compliance
10 program designed to detect and prevent the diversion of controlled substances, inform DEA of
11 suspicious orders required by 21 C.F.R. §1301.74(b), and follow the procedures established by its
12 Controlled Substance Monitoring Program [(‘CSMP’)].”
13

14 749. Despite its 2008 agreement with DEA, McKesson continued to fail to report
15 suspicious orders between 2008 and 2012 and did not fully implement or follow the monitoring
16 program it agreed to. It failed to conduct adequate due diligence of its customers, failed to keep
17 complete and accurate records in the CSMP files maintained for many of its customers and bypassed
18 suspicious order reporting procedures set forth in the CSMP. It failed to take these actions despite
19 its awareness of the great probability that its failure to do so would cause substantial harm.
20

21 750. On January 5, 2017, McKesson entered into an Administrative Memorandum
22 Agreement with the DEA wherein it agreed to pay a \$150 million civil penalty for violation of the
23 2008 McKesson MOA as well as its failure to identify and report suspicious orders at its facilities in
24 Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia
25 MI, Methuen MA, Santa Fe Springs CA, Washington Courthouse OH, and West Sacramento CA.
26 McKesson's 2017 agreement with the DEA documents that McKesson continued to breach its
27
28

1 admitted duties by “fail[ing] to properly monitor its sales of controlled substances and/or report
2 suspicious orders to DEA, in accordance with McKesson’s obligations.”

3 751. As *The Washington Post* and *60 Minutes* recently reported, DEA staff recommended
4 a much larger penalty than the \$150 million ultimately agreed to for McKesson’s continued and
5 renewed breach of its duties, as much as a billion dollars, and delicensing of certain facilities. A
6 DEA memo outlining the investigative findings in connection with the administrative case against 12
7 McKesson distribution centers included in the 2017 settlement stated that McKesson “[s]upplied
8 controlled substances in support of criminal diversion activities”; “[i]gnored blatant diversion”; had
9 a “[p]attern of raising thresholds arbitrarily”; “[f]ailed to review orders or suspicious activity”; and
10 “[i]gnored [the company’s] own procedures designed to prevent diversion.”
11

12 752. On December 17, 2017, CBS aired an episode of *60 Minutes* featuring Assistant
13 Special Agent Schiller, who described McKesson as a company that killed people for its own
14 financial gain and blatantly ignored the CSA requirement to report suspicious orders:
15

16 DAVID SCHILLER: If they would stayed in compliance with their authority and
17 held those that they’re supplying the pills to, the epidemic would be nowhere near
where it is right now. Nowhere near.

18 * * *

19 They had hundreds of thousands of suspicious orders they should have reported, and
20 they didn’t report any. There’s not a day that goes by in the pharmaceutical world, in
the McKesson world, in the distribution world, where there’s not something
suspicious. It happens every day.

21 [INTERVIEWER:] And they had none.

22 DAVID SCHILLER: They weren’t reporting any. I mean, you have to understand
23 that, nothing was suspicious?²⁵³

24 753. Following the 2017 settlement, McKesson shareholders made a books and records
25 request of the company. According to a separate action pending on their behalf, the Company’s
26

27 ²⁵³ Bill Whitaker, *Whistleblowers: DEA Attorneys Went Easy on McKesson, the Country’s Largest*
Drug Distributor, CBS News (Dec. 17, 2017), [https://www.cbsnews.com/news/whistleblowers-](https://www.cbsnews.com/news/whistleblowers-deaattorneys-went-easy-on-mckesson-the-countrys-largest-drug-distributor/)
28 [deaattorneys-went-easy-on-mckesson-the-countrys-largest-drug-distributor/](https://www.cbsnews.com/news/whistleblowers-deaattorneys-went-easy-on-mckesson-the-countrys-largest-drug-distributor/).

1 records show that the Company's Audit Committee failed to monitor McKesson's information
 2 reporting system to assess the state of the Company's compliance with the CSA and McKesson's
 3 2008 settlements. More particularly, the shareholder action alleges that the records show that in
 4 October 2008, the Audit Committee had an initial discussion of the 2008 settlements and results of
 5 internal auditing, which revealed glaring omissions; specifically:

6 (a) some customers had "not yet been assigned thresholds in the system to flag
 7 large shipments of controlled substances for review";

8 (b) "[d]ocumentation evidencing new customer due diligence was incomplete";

9 (c) "documentation supporting the company's decision to change thresholds for
 10 existing customers was also incomplete"; and

11 (d) Internal Audit "identified opportunities to enhance the Standard Operating
 12 Procedures."

13 754. Yet, instead of correcting these deficiencies, the shareholder action's description of
 14 McKesson's internal documents reveals that after that time, for a period of more than four years, the
 15 Audit Committee failed to address the CSMP or perform any more audits of McKesson's
 16 compliance with the CSA or the 2008 settlements. During that period, McKesson's Audit
 17 Committee failed to inquire whether the Company was in compliance with obligations set forth in
 18 those agreements and with the controlled substances regulations more generally. It was only in
 19 January 2013 that the Audit Committee received an Internal Audit report touching on these issues.

20 755. In short, McKesson, was "neither rehabilitated nor deterred by the 2008 [agreement],"
 21 as a DEA official working on the case noted. Quite the opposite, "their bad acts continued and
 22 escalated to a level of egregiousness not seen before." According to statements of "DEA
 23 investigators, agents and supervisors who worked on the McKesson case" reported in the
 24 *Washington Post*, "the company paid little or no attention to the unusually large and frequent orders
 25
 26
 27
 28

1 placed by pharmacies, some of them knowingly supplying the drug rings.” “Instead, the DEA
2 officials said, the company raised its own self-imposed limits, known as thresholds, on orders from
3 pharmacies and continued to ship increasing amounts of drugs in the face of numerous red flags.”

4 756. Since at least 2002, Purdue has maintained a database of health care providers
5 suspected of inappropriately prescribing OxyContin or other opioids. Physicians could be added to
6 this database based on observed indicators of illicit prescribing such as excessive numbers of
7 patients, cash transactions, patient overdoses, and unusual prescribing of the highest strength pills
8 (80 mg OxyContin pills or “80s,” as they were known on the street, were a prime target for
9 diversion). Purdue claims that health care providers added to the database were no longer detailed
10 and that sales representatives received no compensation tied to these providers’ prescriptions.

11 757. Yet, Purdue failed to cut off these providers’ opioid supply at the pharmacy level –
12 meaning Purdue continued to generate sales revenue from their prescriptions – and failed to report
13 these providers to state medical boards or law enforcement. Purdue’s former senior compliance
14 officer acknowledged in an interview with the *Los Angeles Times* that in five years of investigating
15 suspicious pharmacies, the company never stopped the supply of its opioids to a pharmacy, even
16 where Purdue employees personally witnessed the diversion of its drugs.

17 758. The same was true of prescribers. For example, as discussed above, despite Purdue’s
18 knowledge of illicit prescribing from one Los Angeles clinic which its district manager called an
19 “organized drug ring” in 2009, Purdue did not report its suspicions until long after law enforcement
20 shut it down and not until the ring prescribed more than 1.1 million OxyContin tablets.

21 759. The New York Attorney General found that Purdue placed 103 New York health care
22 providers on its “No-Call” List between January 1, 2008 and March 7, 2015, and yet that Purdue’s
23 sales representatives had detailed approximately two-thirds of these providers, some quite
24 extensively, making more than a total of 1,800 sales calls to their offices over a six-year period.

1 760. The New York Attorney General similarly found that Endo knew, as early as 2011,
 2 that Opana ER was being abused in New York, but certain sales representatives who detailed New
 3 York health care providers testified that they did not know about any policy or duty to report
 4 problematic conduct. The New York Attorney General further determined that Endo detailed health
 5 care providers who were subsequently arrested or convicted for illegal prescribing of opioids a total
 6 of 326 times, and these prescribers collectively wrote 1,370 prescriptions for Opana ER (although
 7 the subsequent criminal charges at issue did not involve Opana ER).
 8

9 761. As all of the governmental actions against the Marketing Defendants and against all
 10 the Defendants show, Defendants knew that their actions were unlawful, and yet deliberately refused
 11 to change their practices because compliance with their legal obligations would have decreased their
 12 sales and their profits.
 13

14 **V. FACTS PERTAINING TO CLAIMS UNDER RACKETEER-
 INFLUENCED AND CORRUPT ORGANIZATIONS (“RICO”) ACT**

15 **A. The Opioid Marketing Enterprise**

16 **1. The Common Purpose and Scheme of the Opioid Marketing
 Enterprise**
 17

18 762. Knowing that their products were highly addictive, ineffective and unsafe for the
 19 treatment of long-term chronic pain, and non-acute and non-cancer pain, the RICO Marketing
 20 Defendants²⁵⁴ formed an association-in-fact enterprise and engaged in a scheme to unlawfully
 21 increase their profits and sales, and grow their share of the prescription painkiller market, through
 22 repeated and systematic misrepresentations about the safety and efficacy of opioids for treating long-
 23 term chronic pain.
 24

25 763. In order to unlawfully increase the demand for opioids, the RICO Marketing
 26 Defendants formed an association-in-fact enterprise (the “Opioid Marketing Enterprise”) with the

27 ²⁵⁴ The RICO Marketing Defendants referred to in this section are those named in Count I for
 28 violation of 18 U.S.C. §1961 *et seq.*, including Purdue, Cephalon, Janssen, Endo, and Mallinckrodt.

1 Front Groups and KOLs described above. Through their personal relationships, the members of the
2 Opioid Marketing Enterprise had the opportunity to form and take actions in furtherance of the
3 Opioid Marketing Enterprise's common purpose. The RICO Marketing Defendants' substantial
4 financial contribution to the Opioid Marketing Enterprise, and the advancement of opioids-friendly
5 messaging, fueled the U.S. opioids epidemic.
6

7 764. The RICO Marketing Defendants, through the Opioid Marketing Enterprise,
8 concealed the true risks and dangers of opioids from the medical community and the public, and San
9 Francisco, and made misleading statements and misrepresentations about opioids that downplayed
10 the risk of addiction and exaggerated the benefits of opioid use. The misleading statements
11 included: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can
12 be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually
13 symptoms of an invented condition the RICO Marketing Defendants named "pseudoaddiction";
14 (4) that withdrawal is easily managed; (5) that increased dosing presents no significant risks; (6) that
15 long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment
16 are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents
17 addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse.
18

19 765. The scheme devised, implemented and conducted by the RICO Marketing Defendants
20 was a common course of conduct designed to ensure that the RICO Marketing Defendants
21 unlawfully increased their sales and profits through concealment and misrepresentations about the
22 addictive nature and effective use of the RICO Marketing Defendants' drugs. The RICO Marketing
23 Defendants, the Front Groups, and the KOLs acted together for a common purpose and perpetuated
24 the Opioid Marketing Enterprise's scheme, including through the unbranded promotion and
25 marketing network as described above.
26
27
28

1 766. There was regular communication between the RICO Marketing Defendants, Front
2 Groups, and KOLs in which information was shared, misrepresentations were coordinated, and
3 payments were exchanged. Typically, the coordination, communication and payments occurred, and
4 continue to occur, through the repeated and continuing use of the wires and mail in which the RICO
5 Marketing Defendants, Front Groups, and KOLs share information regarding overcoming objections
6 and resistance to the use of opioids for chronic pain. The RICO Marketing Defendants, Front
7 Groups, and KOLs functioned as a continuing unit for the purpose of implementing the Opioid
8 Marketing Enterprise's scheme and common purpose, and each agreed and took actions to hide the
9 scheme and continue its existence.
10

11 767. At all relevant times, the Front Groups were aware of the RICO Marketing
12 Defendants' conduct and were knowing and willing participants in and beneficiaries of that conduct.
13 Each Front Group also knew, but did not disclose, that the other Front Groups were engaged in the
14 same scheme, to the detriment of consumers, prescribers, and San Francisco. But for the Opioid
15 Marketing Enterprise's unlawful fraud, the Front Groups would have had incentive to disclose the
16 deceit by the RICO Marketing Defendants and the Opioid Marketing Enterprise to their members
17 and constituents. By failing to disclose this information, Front Groups perpetuated the Opioid
18 Marketing Enterprise's scheme and common purpose, and reaped substantial benefits.
19

20 768. At all relevant times, the KOLs were aware of the RICO Marketing Defendants'
21 conduct, were knowing and willing participants in that conduct, and reaped benefits from that
22 conduct. The RICO Marketing Defendants selected KOLs solely because they favored the
23 aggressive treatment of chronic pain with opioids. The RICO Marketing Defendants' support helped
24 the KOLs become respected industry experts. And, as they rose to prominence, the KOLs falsely
25 touted the benefits of using opioids to treat chronic pain, repaying the RICO Marketing Defendants
26 by advancing their marketing goals. The KOLs also knew, but did not disclose, that the other KOLS
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28

1 and Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and
2 San Francisco. But for the Opioid Marketing Enterprise's unlawful conduct, the KOLs would have
3 had incentive to disclose the deceit by the RICO Marketing Defendants and the Opioid Marketing
4 Enterprise, and to protect their patients and the patients of other physicians. By failing to disclose
5 this information, KOLs furthered the Opioid Marketing Enterprise's scheme and common purpose,
6 and reaped substantial benefits.

7
8 769. As public scrutiny and media coverage focused on how opioids ravaged communities
9 in San Francisco and throughout the United States, the Front Groups and KOLS did not challenge
10 the RICO Marketing Defendants' misrepresentations, seek to correct their previous
11 misrepresentations, terminate their role in the Opioid Marketing Enterprise, or disclose publicly that
12 the risks of using opioids for chronic pain outweighed their benefits and were not supported by
13 medically acceptable evidence.

14
15 770. The RICO Marketing Defendants, Front Groups and KOLs engaged in certain
16 discrete categories of activities in furtherance of the common purpose of the Opioid Marketing
17 Enterprise. As described herein, the Opioid Marketing Enterprise's conduct in furtherance of the
18 common purpose of the Opioid Marketing Enterprise involved: (1) misrepresentations regarding the
19 risk of addiction and safe use of prescription opioids for long-term chronic pain (described in detail
20 above); (2) lobbying to defeat measures to restrict over-prescription; (3) efforts to criticize or
21 undermine CDC guidelines; and (4) efforts to limit prescriber accountability.

22
23 771. In addition to disseminating misrepresentations about the risks and benefits of
24 opioids, the Opioid Marketing Enterprise also furthered its common purpose by criticizing or
25 undermining the CDC Guideline. Members of the Opioid Marketing Enterprise criticized or
26
27
28

1 undermined the CDC Guideline, which “an important step – and perhaps the first major step from
2 the federal government – toward limiting opioid prescriptions for chronic pain.”²⁵⁵

3 772. Several Front Groups, including the USPF and the AAPM, criticized the draft
4 guidelines in 2015, arguing that the “CDC slides presented on Wednesday were not transparent
5 relative to process and failed to disclose the names, affiliation, and conflicts of interest of the
6 individuals who participated in the construction of these guidelines.”

7
8 773. The AAPM criticized the prescribing guidelines in 2016, through its immediate past
9 president, stating “that the CDC guideline makes disproportionately strong recommendations based
10 upon a narrowly selected portion of the available clinical evidence.”

11 774. The RICO Marketing Defendants alone could not have accomplished the purpose of
12 the Opioid Marketing Enterprise without the assistance of the Front Groups and KOLs, who were
13 perceived as “neutral” and more “scientific” than the RICO Marketing Defendants themselves.
14 Without the work of the Front Groups and KOLs in spreading misrepresentations about opioids, the
15 Opioid Marketing Enterprise could not have achieved its common purpose.
16

17 775. The impact of the Opioid Marketing Enterprise’s scheme is still in place – *i.e.*, the
18 opioids continue to be prescribed and used for chronic pain throughout the area of San Francisco,
19 and the epidemic continues to injure San Francisco and consume the resources of San Francisco’s
20 public health, safety, and support systems.
21

22 776. As a result, it is clear that the RICO Marketing Defendants, the Front Groups, and the
23 KOLs were each willing participants in the Opioid Marketing Enterprise, had a common purpose and
24

25
26 ²⁵⁵ *Fueling an Epidemic, Report Two: Exposing the Financial Ties Between Opioid Manufacturers*
27 *and Third-Party Advocacy Groups*, U.S. Senate Homeland Security & Governmental Affairs
28 Committee, Ranking Member’s Office at 13 (Feb. 13, 2018), <https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20Epidemic-Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Party%20Advocacy%20Groups.pdf>.

1 interest in the object of the scheme, and functioned within a structure designed to effectuate the
 2 Opioid Marketing Enterprise's purpose.

3 **2. The Conduct of the Opioid Marketing Enterprise Violated** 4 **Civil RICO**

5 777. From approximately the late 1990s to the present, each of the RICO Marketing
 6 Defendants exerted control over the Opioid Marketing Enterprise and participated in the operation or
 7 management of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following
 8 ways:

9 (a) Creating and providing a body of deceptive, misleading and unsupported
 10 medical and popular literature about opioids that (i) understated the risks and overstated the benefits
 11 of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus
 12 more likely to be relied upon by physicians, patients, and payors;

13 (b) Creating and providing a body of deceptive, misleading and unsupported
 14 electronic and print advertisements about opioids that (i) understated the risks and overstated the
 15 benefits of long-term use; (ii) appeared to be the result of independent, objective research; and
 16 (iii) was thus more likely to be relied upon by physicians, patients, and payors;

17 (c) Creating and providing a body of deceptive, misleading and unsupported sales
 18 and promotional training materials about opioids that (i) understated the risks and overstated the
 19 benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii)
 20 were thus more likely to be relied upon by physicians, patients, and payors;

21 (d) Creating and providing a body of deceptive, misleading and unsupported
 22 CMEs and speaker presentations about opioids that (i) understated the risks and overstated the
 23 benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii)
 24 were thus more likely to be relied upon by physicians, patients, and payors;

1 (e) Selecting, cultivating, promoting and paying KOLs based solely on their
2 willingness to communicate and distribute the RICO Marketing Defendants' messages about the use
3 of opioids for chronic pain;

4 (f) Providing substantial opportunities for KOLs to participate in research studies
5 on topics the RICO Marketing Defendants suggested or chose, with the predictable effect of ensuring
6 that many favorable studies appeared in the academic literature;

7 (g) Paying KOLs to serve as consultants or on the RICO Marketing Defendants'
8 advisory boards, on the advisory boards and in leadership positions on Front Groups, and to give
9 talks or present CMEs, typically over meals or at conferences;

10 (h) Selecting, cultivating, promoting, creating and paying Front Groups based
11 solely on their willingness to communicate and distribute the RICO Marketing Defendants'
12 messages about the use of opioids for chronic pain;

13 (i) Providing substantial opportunities for Front Groups to participate in and/or
14 publish research studies on topics the RICO Marketing Defendants suggested or chose (and paid
15 for), with the predictable effect of ensuring that many favorable studies appeared in the academic
16 literature;

17 (j) Paying significant amounts of money to the leaders and individuals associated
18 with Front Groups;

19 (k) Donating to Front Groups to support talks or CMEs, which were typically
20 presented over meals or at conferences;

21 (l) Disseminating many of their false, misleading, imbalanced, and unsupported
22 statements through unbranded materials that appeared to be independent publications from Front
23 Groups;

1 (m) Sponsoring CME programs put on by Front Groups that focused exclusively
2 on the use of opioids for chronic pain;

3 (n) Developing and disseminating pro-opioid treatment guidelines with the help
4 of the KOLs as authors and promoters, and the help of the Front Groups as publishers and
5 supporters;

6 (o) Encouraging Front Groups to disseminate their pro-opioid messages to groups
7 targeted by the RICO Marketing Defendants, such as veterans and the elderly, and then funding that
8 distribution;

9 (p) Concealing their relationship to and control of Front Groups and KOLs from
10 San Francisco and the public at large; and

11 (q) Intending that Front Groups and KOLs would distribute through the U.S. mail
12 and interstate wire facilities, promotional and other materials that claimed opioids could be safely
13 used for chronic pain.
14

15
16 778. The Opioid Marketing Enterprise had a hierarchical decision-making structure that
17 was headed by the RICO Marketing Defendants and corroborated by the KOLs and Front Groups.
18 The RICO Marketing Defendants controlled representations made about their opioids and their
19 drugs, doled out funds to pharmacy benefits managers and payments to KOLs, and ensured that
20 representations made by KOLs, Front Groups, and the RICO Marketing Defendants' sales detailers
21 were consistent with the Marketing Defendants' messaging throughout the United States, California,
22 and San Francisco. The Front Groups and KOLS in the Opioid Marketing Enterprise were
23 dependent on the RICO Marketing Defendants for their financial structure and for career
24 development and promotion opportunities.
25

26 779. The Front Groups also conducted and participated in the conduct of the Opioid
27 Marketing Enterprise, directly or indirectly, in the following ways:
28

1 (a) The Front Groups promised to, and did, make representations regarding
2 opioids and the RICO Marketing Defendants' drugs that were consistent with the RICO Marketing
3 Defendants' messages;

4 (b) The Front Groups distributed, through the U.S. Mail and interstate wire
5 facilities, promotional and other materials that claimed opioids could be safely used for chronic pain
6 without addiction and misrepresented that the benefits of using opioids for chronic pain outweighed
7 the risks;

9 (c) The Front Groups echoed and amplified messages favorable to increased
10 opioid use, and ultimately, the financial interests of the RICO Marketing Defendants;

11 (d) The Front Groups issued guidelines and policies minimizing the risk of opioid
12 addiction and promoting opioids for chronic pain;

14 (e) The Front Groups strongly criticized the 2016 guidelines from the CDC that
15 recommended limits on opioid prescriptions for chronic pain; and

16 (f) The Front Groups concealed their connections to the KOLs and the RICO
17 Marketing Defendants.

18 780. The RICO Marketing Defendants' Front Groups, "with 'their large numbers and
19 credibility with policymakers and the public' – have 'extensive influence in specific disease areas.'"
20 The larger Front Groups "likely have a substantial effect on policies relevant to their industry
21 sponsors."²⁵⁶ "By aligning medical culture with industry goals in this way, many of the groups
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26 ²⁵⁶ U.S. Senate Homeland Security & Government Affairs Committee, *Fueling an Epidemic:*
27 *Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*,
28 Minority Staff Report 2 (Feb. 12, 2018) at 2, <https://www.hsgac.senate.gov/download/fueling-an-epidemic-exposing-the-financial-ties-between-opioid-manufacturers-and-third-party-advocacy-groups>.

1 described in this report may have played a significant role in creating the necessary conditions for
2 the U.S. opioid epidemic.”²⁵⁷

3 781. The KOLs also participated in the conduct of the affairs of the Opioid Marketing
4 Enterprise, directly or indirectly, in the following ways:

5 (a) The KOLs promised to, and did, make representations regarding opioids and
6 the RICO Marketing Defendants’ drugs that were consistent with the RICO Marketing Defendants’
7 messages themselves;

8 (b) The KOLs distributed, through the U.S. Mail and interstate wire facilities,
9 promotional and other materials that claimed opioids could be safely used for chronic pain without
10 addiction and misrepresented that the benefits of using opioids for chronic pain outweighed the risks;

11 (c) The KOLs echoed and amplified messages favorable to increased opioid use,
12 and ultimately, the financial interests of the RICO Marketing Defendants;

13 (d) The KOLs issued guidelines and policies minimizing the risk of opioid
14 addiction and promoting opioids for chronic pain;

15 (e) The KOLs strongly criticized the 2016 guidelines from the CDC that
16 recommended limits on opioid prescriptions for chronic pain; and

17 (f) The KOLs concealed their connections to the Front Groups and the RICO
18 Marketing Defendants, and their sponsorship by the RICO Marketing Defendants.

19 782. The scheme devised and implemented by the RICO Marketing Defendants and
20 members of the Opioid Marketing Enterprise amounted to a common course of conduct intended to
21 increase the RICO Marketing Defendants’ sales from prescription opioids by encouraging the
22 prescribing and use of opioids for long-term chronic pain. The scheme was a continuing course of
23 conduct, and many aspects of it continue through to the present.
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28 ²⁵⁷ *Id.* at 1.

1 **3. The RICO Marketing Defendants Controlled and Paid Front**
2 **Groups and KOLs to Promote and Maximize Opioid Use**

3 783. As discussed in detail above, the RICO Marketing Defendants funded and controlled
4 the various Front Groups, including APF, AAPM/APS, FSMB, Alliance for Patient Access, USPF,
5 and AGS. The Front Groups, which appeared to be independent, but were not, transmitted the RICO
6 Marketing Defendants' misrepresentations. The RICO Marketing Defendants and the Front Groups
7 thus worked together to promote the goals of the Opioid Marketing Enterprise.

8 784. The RICO Marketing Defendants worked together with each other through the Front
9 Groups that they jointly funded and through which they collaborated on the joint promotional
10 materials described above.

11 785. Similarly, as discussed in detail above, the RICO Marketing Defendants paid KOLs,
12 including Drs. Portenoy, Fine, Fishman, and Webster, to spread their misrepresentations and
13 promote their products. The RICO Marketing Defendants and the KOLs thus worked together to
14 promote the goals of the Opioid Marketing Enterprise.
15

16 **4. Pattern of Racketeering Activity**

17 786. The RICO Marketing Defendants' scheme described herein was perpetrated, in part,
18 through multiple acts of mail fraud and wire fraud, constituting a pattern of racketeering activity as
19 described herein.
20

21 787. The pattern of racketeering activity used by the RICO Marketing Defendants and the
22 Opioid Marketing Enterprise likely involved thousands of separate instances of the use of the U.S.
23 Mail or interstate wire facilities in furtherance of the unlawful Opioid Marketing Enterprise,
24 including essentially uniform misrepresentations, concealments and material omissions regarding the
25 beneficial uses and non-addictive qualities for the long-term treatment of chronic, non-acute and
26 non-cancer pain, with the goal of profiting from increased sales of the RICO Marketing Defendants'
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28

1 drugs induced by consumers, prescribers, regulators and San Francisco's reliance on the RICO
2 Marketing Defendants' misrepresentations.

3 788. Each of these fraudulent mailings and interstate wire transmissions constitutes
4 racketeering activity and, collectively, these violations constitute a pattern of racketeering activity
5 through which the RICO Marketing Defendants, the Front Groups and the KOLs defrauded and
6 intended to defraud San Francisco, residents and consumers in San Francisco, and other intended
7 victims.
8

9 789. The RICO Marketing Defendants devised and knowingly carried out an illegal
10 scheme and artifice to defraud by means of materially false or fraudulent pretenses, representations,
11 promises, or omissions of material facts regarding the safe, non-addictive and effective use of
12 opioids for long-term chronic, non-acute and non-cancer pain. The RICO Marketing Defendants and
13 members of the Opioid Marketing Enterprise knew that these representations violated the FDA-
14 approved use these drugs, and were not supported by actual evidence. The RICO Marketing
15 Defendants intended that that their common purpose and scheme to defraud would, and did, use the
16 U.S. Mail and interstate wire facilities, intentionally and knowingly with the specific intent to
17 advance, and for the purpose of executing, their illegal scheme.
18

19 790. By intentionally concealing the material risks and affirmatively misrepresenting the
20 benefits of using opioids for chronic pain to prescribers, regulators, the public, and San Francisco,
21 the RICO Marketing Defendants, the Front Groups and the KOLs engaged in a fraudulent and
22 unlawful course of conduct constituting a pattern of racketeering activity.
23

24 791. The RICO Marketing Defendants' use of the U.S. Mail and interstate wire facilities to
25 perpetrate the opioids marketing scheme involved thousands of communications, publications,
26 representations, statements, electronic transmissions, and payments, including, *inter alia*:
27
28

1 (a) Marketing materials about opioids, and their risks and benefits, which the
2 RICO Marketing Defendants sent to health care providers, transmitted through the Internet and
3 television, published, and transmitted to Front Groups and KOLs located across the country,
4 including in San Francisco;

5 (b) Written representations and telephone calls between the RICO Marketing
6 Defendants and Front Groups regarding the misrepresentations, marketing statements and claims
7 about opioids, including their non-addictive, safe use for chronic long-term pain generally;

8 (c) Written representations and telephone calls between the RICO Marketing
9 Defendants and KOLs regarding the misrepresentations, marketing statements and claims about
10 opioids, including their non-addictive, safe use for chronic long-term pain generally;

11 (d) E-mail, telephone and written communications between the RICO Marketing
12 Defendants and the Front Groups agreeing to or implementing the opioids marketing scheme;

13 (e) E-mail, telephone and written communications between the RICO Marketing
14 Defendants and the KOLs agreeing to or implementing the opioids marketing scheme;

15 (f) Communications between the RICO Marketing Defendants, Front Groups and
16 the media regarding publication, drafting of treatment guidelines, and the dissemination of the same
17 as part of the Opioid Marketing Enterprise;

18 (g) Communications between the RICO Marketing Defendants, KOLs and the
19 media regarding publication, drafting of treatment guidelines, and the dissemination of the same as
20 part of the Opioid Marketing Enterprise;

21 (h) Written and oral communications directed to state and local agencies, federal
22 and state courts, and private insurers throughout the State of California and San Francisco that
23 fraudulently misrepresented the risks and benefits of using opioids for chronic pain; and
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1 (i) Receipts of increased profits sent through the U.S. Mail and interstate wire
2 facilities – the wrongful proceeds of the scheme.

3 792. In addition to the above-referenced predicate acts, it was intended by and foreseeable
4 to the RICO Marketing Defendants that the Front Groups and the KOLs would distribute
5 publications through the U.S. Mail and by interstate wire facilities and, in those publications, claim
6 that the benefits of using opioids for chronic pain outweighed the risks of doing so.

7
8 793. To achieve the common goal and purpose of the Opioid Marketing Enterprise, the
9 RICO Marketing Defendants and members of the Opioid Marketing Enterprise hid from consumers,
10 prescribers, regulators, and San Francisco: (a) the fraudulent nature of the RICO Marketing
11 Defendants' marketing scheme; (b) the fraudulent nature of statements made by the RICO Marketing
12 Defendants and by their KOLs, Front Groups and other third parties regarding the safety and
13 efficacy of prescription opioids; and (c) the true nature of the relationship between the members of
14 the Opioid Marketing Enterprise.

15
16 794. The RICO Marketing Defendants and each member of the Opioid Marketing
17 Enterprise agreed, with knowledge and intent, to the overall objective of the RICO Marketing
18 Defendants' fraudulent scheme and participated in the common course of conduct to commit acts of
19 fraud and indecency in marketing prescription opioids.

20
21 795. Indeed, for the RICO Marketing Defendants' fraudulent scheme to work, each of
22 them had to agree to implement similar tactics regarding the fraudulent marketing of prescription
23 opioids. This conclusion is supported by the fact that the RICO Marketing Defendants each
24 financed, supported, and worked through the same KOLs and Front Groups, and often collaborated
25 on and mutually supported the same publications, CMEs, presentations, and prescription guidelines

26 796. The RICO Marketing Defendants' predicate acts all had the purpose of creating the
27 opioid epidemic that substantially injured San Francisco's business and property, while
28

1 simultaneously generating billion-dollar revenues and profits for the RICO Marketing Defendants.
 2 The predicate acts were committed or caused to be committed by the RICO Marketing Defendants
 3 through their participation in the Opioid Marketing Enterprise and in furtherance of its fraudulent
 4 scheme.

5 **B. The Opioid Supply Chain Enterprise**

6 797. Faced with the reality that they will now be held accountable for the consequences of
 7 the opioid epidemic they created, members of the industry resort to “a categorical denial of any
 8 criminal behavior or intent.”²⁵⁸ Defendants’ actions went far beyond what could be considered
 9 ordinary business conduct. For more than a decade, certain Defendants, the “RICO Supply Chain
 10 Defendants” (Purdue, Cephalon, Endo, Mallinckrodt, Actavis, McKesson, Cardinal, Anda, and
 11 AmerisourceBergen) worked together in an illicit enterprise, engaging in conduct that was not only
 12 illegal, but in certain respects anti-competitive, with the common purpose and achievement of vastly
 13 increasing their respective profits and revenues by exponentially expanding a market that the law
 14 intended to restrict (the “Opioid Supply Chain Enterprise”).

15 798. Knowing that dangerous drugs have a limited place in our society, and that their
 16 dissemination and use must be vigilantly monitored and policed to prevent the harm that drug abuse
 17 and addiction causes to individuals, society and governments, Congress enacted the Controlled
 18 Substances Act. Specifically, through the CSA, which created a closed system of distribution for
 19 controlled substances, Congress established an enterprise for good. CSA imposes a reporting duty
 20 that cuts across company lines. Regulations adopted under the CSA require that companies who are
 21 entrusted with permission to operate within this system cannot simply operate as competitive in an
 22 “anything goes” profit-maximizing market. Instead, the statute tasks them to watch over each other
 23
 24
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 27 ²⁵⁸ *McKesson Responds to Recent 60 Minutes Story*, Business Wire (Dec. 18, 2017)
 28 <http://www.businesswire.com/news/home/20171217005108/en/mckesson-responds-60-minutes-story>.

1 with a careful eye for suspicious activity. Driven by greed, Defendants betrayed that trust and
2 subverted the constraints of the CSA's closed system to conduct their own enterprise for evil.

3 799. As "registrants" under the CSA, the RICO Supply Chain Defendants are duty bound
4 to identify and report "orders of unusual size, orders deviating substantially from a normal pattern,
5 and orders of unusual frequency."²⁵⁹ Critically, the RICO Supply Chain Defendants' responsibilities
6 do not end with the products they manufacture or distribute – there is no such limitation in the law
7 because their duties cut across company lines. Thus, when the RICO Supply Chain Defendants
8 obtain information about the sales and distribution of other companies' opioid products, as they did
9 through data mining companies like IMS Health, they were legally obligated to report that activity to
10 the DEA.
11

12 800. If morality and the law did not suffice, competition dictates that the RICO Supply
13 Chain Defendants would turn in their rivals when they had reason to suspect suspicious activity.
14 Indeed, if a manufacturer or distributor could gain market share by reporting a competitor's illegal
15 behavior (causing it to lose a license to operate, or otherwise inhibit its activity), ordinary business
16 conduct dictates that it would do so. Under the CSA this whistleblower or watchdog function is not
17 only a protected choice, but a statutory mandate. Unfortunately, however, that is not what happened.
18 Instead, knowing that investigations into potential diversion would only lead to shrinking markets,
19 the Rico Supply Chain Defendants elected to operate in a conspiracy of silence, in violation of both
20 the CSA and RICO.
21

22 801. The RICO Supply Chain Defendants' scheme required the participation of all. If any
23 one member broke rank, its compliance activities would highlight deficiencies of the others, and the
24 artificially high quotas they maintained through their scheme would crumble. But, if all the
25 members of the enterprise conducted themselves in the same manner, it would be difficult for the
26

27
28 ²⁵⁹ 21 C.F.R. §1301.74(b).

1 DEA to go after any one of them. Accordingly, through the connections they made as a result of
2 their participation in the HDA, the RICO Supply Chain Defendants chose to flout the closed system
3 designed to protect the citizens. Publicly, in 2008, they announced their formulation of *Industry*
4 *Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled*
5 *Substances*. But, privately, the RICO Supply Chain Defendants refused to act and, through their
6 lobbying efforts, collectively sought to undermine the impact of the CSA. Indeed, despite the
7 issuance of these Industry Compliance Guidelines, which recognize the RICO Supply Chain
8 Defendants' duties under the law, as illustrated by the subsequent industry-wide enforcement actions
9 and consent orders issued after that time, none of them complied. John Gray, president and CEO of
10 the HDA, said to Congress in 2014, it is "difficult to find the right balance between proactive anti-
11 diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed
12 medications." Yet, the RICO Supply Chain Defendants apparently all found the same profit-
13 maximizing balance – intentionally remaining silent to ensure the largest possible financial return.

14
15
16 802. As described above, at all relevant times, the RICO Supply Chain Defendants
17 operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales,
18 revenues and profits by fraudulently increasing the quotas set by the DEA that would allow them to
19 collectively benefit from a greater pool of prescription opioids to manufacture and distribute. In
20 support of this common purpose and fraudulent scheme, the RICO Supply Chain Defendants jointly
21 agreed to disregard their statutory duties to identify, investigate, halt and report suspicious orders of
22 opioids and diversion of their drugs into the illicit market so that those orders would not result in a
23 decrease, or prevent an increase in, the necessary quotas.

24
25 803. At all relevant times, as described above, the RICO Supply Chain Defendants exerted
26 control over, conducted and/or participated in the Opioid Supply Chain Enterprise by fraudulently
27 claiming that they were complying with their duties under the CSA to identify, investigate and report
28

1 suspicious orders of opioids in order to prevent diversion of those highly addictive substances into
 2 the illicit market, and to halt such unlawful sales, so as to increase production quotas and generate
 3 unlawful profits, as follows:

4 804. The RICO Supply Chain Defendants disseminated false and misleading statements to
 5 state and federal regulators claiming that:

- 6 (a) the quotas for prescription opioids should be increased;
- 7 (b) they were complying with their obligations to maintain effective controls
 8 against diversion of their prescription opioids;
- 9 (c) they were complying with their obligations to design and operate a system to
 10 disclose to the registrant suspicious orders of their prescription opioids;
- 11 (d) they were complying with their obligation to notify the DEA of any suspicious
 12 orders or diversion of their prescription opioids; and
- 13 (e) they did not have the capability to identify suspicious orders of controlled
 14 substances.

15 805. The Defendants applied political and other pressure on the DOJ and DEA to halt
 16 prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to
 17 strip the DEA of its ability to immediately suspend registrations pending investigation by passing the
 18 “Ensuring Patient Access and Effective Drug Enforcement Act.”²⁶⁰

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 22 ²⁶⁰ *HDMA is Now the Healthcare Distribution Alliance*, Pharmaceutical Commerce,
 23 [http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-](http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/)
 24 [alliance/](http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/) (last updated July 6, 2016); Lenny Bernstein & Scott Higham, *Investigation: The DEA*
 25 *slowed enforcement while the opioid epidemic grew out of control*, Wash. Post (Oct. 22, 2016),
 26 [https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-](https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html)
 27 [epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html](https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html);
 28 Lenny Bernstein & Scott Higham, *U.S. senator calls for investigation of DEA enforcement*
slowdown amid opioid crisis, Wash. Post (Mar. 6, 2017), [https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/](https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html)
[5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html](https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html); Eric Eyre, *DEA agent: “we had no*
leadership” in WV amid flood of pain pills, Charleston Gazette-Mail (Feb. 18, 2017),
[http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-](http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-)
[of-pain-pills-](http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-).

1 806. The CSA and the Code of Federal Regulations require the RICO Supply Chain
2 Defendants to make reports to the DEA of any suspicious orders identified through the design and
3 operation of their system to disclose suspicious orders. The failure to make reports as required by
4 the CSA and Code of Federal Regulations amounts to a criminal violation of the statute.

5 807. The RICO Supply Chain Defendants knowingly and intentionally furnished false or
6 fraudulent information in their reports to the DEA about suspicious orders and/or omitted material
7 information from reports, records and other document required to be filed with the DEA, including
8 the Marketing Defendants' applications for production quotas. Specifically, the RICO Supply Chain
9 Defendants were aware of suspicious orders of prescription opioids and the diversion of their
10 prescription opioids into the illicit market, and failed to report this information to the DEA in their
11 mandatory reports and their applications for production quotas.

12 808. The RICO Supply Chain Defendants used, directed the use of, and/or caused to be
13 used, thousands of interstate mail and wire communications in service of their scheme through
14 virtually uniform misrepresentations, concealments and material omissions regarding their
15 compliance with their mandatory reporting requirements and the actions necessary to carry out their
16 unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of
17 opioids into the illicit market.

18 809. In devising and executing the illegal scheme, the RICO Supply Chain Defendants
19 devised and knowingly carried out a material scheme and/or artifice to defraud by means of
20 materially false or fraudulent pretenses, representations, promises, or omissions of material facts.

21 810. For the purpose of executing the illegal scheme, the RICO Supply Chain Defendants
22 committed racketeering acts, which number in the thousands, intentionally and knowingly with the
23 specific intent to advance the illegal scheme. These racketeering acts, which included repeated acts
24 of mail fraud and wire fraud, constituted a pattern of racketeering.

1 811. The RICO Supply Chain Defendants' use of the mail and wires includes, but is not
 2 limited to, the transmission, delivery, or shipment of the following by the Marketing Defendants, the
 3 Distributor Defendants, or third parties that were foreseeably caused to be sent as a result of the
 4 RICO Supply Chain Defendants' illegal scheme, including but not limited to:

5 (a) The prescription opioids themselves;
 6
 7 (b) Documents and communications that supported and/or facilitated the RICO
 8 Supply Chain Defendants' request for higher aggregate production quotas, individual production
 9 quotas, and procurement quotas;

10 (c) Documents and communications that facilitated the manufacture, purchase
 11 and sale of prescription opioids;

12 (d) The RICO Supply Chain Defendants' DEA registrations;

13 (e) Documents and communications that supported and/or facilitated the RICO
 14 Supply Chain Defendants' DEA registrations;

15 (f) The RICO Supply Chain Defendants' records and reports that were required to
 16 be submitted to the DEA pursuant to 21 U.S.C. §827;

17 (g) Documents and communications related to the RICO Supply Chain
 18 Defendants' mandatory DEA reports pursuant to 21 U.S.C. §823 and 21 C.F.R. §1301.74;

19 (h) Documents intended to facilitate the manufacture and distribution of the RICO
 20 Supply Chain Defendants' prescription opioids, including bills of lading, invoices, shipping records,
 21 reports and correspondence;

22 (i) Documents for processing and receiving payment for prescription opioids;

23 (j) Payments from the distributors to the Marketing Defendants;

24 (k) Rebates and chargebacks from the Marketing Defendants to the Distributors
 25 Defendants;

(l) Payments to the RICO Supply Chain Defendants' lobbyists through the PCF;

(m) Payments to the RICO Supply Chain Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;

(n) Deposits of proceeds from the RICO Supply Chain Defendants' manufacture and distribution of prescription opioids; and

(o) Other documents and things, including electronic communications.

812. The RICO Supply Chain Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce, including the following:

Defendant Group Name	Company Names	Drugs		
		Drug Name	Chemical Name	CSA Schedule
Purdue	(1) Purdue Pharma, LP, (2) Purdue Pharma, Inc., (3) The Purdue Frederick Company	OxyContin	Oxycodone hydrochloride extended release	Schedule II
		MS Contin	Morphine sulfate extended release	Schedule II
		Dilaudid	Hydromorphone hydrochloride	Schedule II
		Dilaudid-HP	Hydromorphone hydrochloride	Schedule II
		Butrans	Buprenorphine	Schedule II
		Hysinga ER	Hydrocodone bitrate	Schedule II
		Targiniq ER	Oxycodone hydrochloride	Schedule II
Cephalon	(1) Cephalon, Inc., (2) Teva Pharmaceutical Industries, Ltd., (3) Teva Pharmaceuticals USA, Inc.	Actiq	Fentanyl citrate	Schedule II
		Fentora	Fentanyl citrate	Schedule II
		Generic oxycodone	Oxycodone hydrochloride	Schedule II
Endo	(1) Endo Health Solutions, Inc., (2) Endo Pharmaceuticals Inc., (3) Qualitest Pharmaceuticals, Inc. (<i>wholly-owned subsidiary of Endo</i>)	Opana ER	Oxymorphone hydrochloride extended release	Schedule II
		Opana	Oxymorphone hydrochloride	Schedule II
		Percodan	Oxymorphone hydrochloride and aspirin	Schedule II

Defendant Group Name	Company Names	Drugs		
		Percocet	Oxymorphone hydrochloride and acetaminophen	Schedule II
		Generic oxycodone		Schedule II
		Generic oxymorphone		Schedule II
		Generic hydromorphone		Schedule II
		Generic hydrocodone		Schedule II
Mallinckrodt	(1) Mallinckrodt plc, (2) Mallinckrodt LLC (wholly-owned subsidiary of Mallinckrodt plc)	Exalgo	Hydromorphone hydrochloride	Schedule II
		Roxicodone	Oxycodone hydrochloride	Schedule II
Actavis	(1) Allergan Plc, (2) Allergan Finance, LLC (3) Actavis LLC, (4) Actavis Pharma, Inc., (5) Actavis Plc, (6) Actavis, Inc., (7) Actavis Inc., (8) Watson Pharmaceuticals, Inc., (9) Watson Pharma, Inc.	Kadian	Morphine Sulfate	Schedule II
		Norco (generic of Kadian)	Hydrocodone and acetaminophen	Schedule II
		Generic Duragesic	Fentanyl	Schedule II
		Generic Opana	Oxymorphone hydrochloride	Schedule II

813. Each of the RICO Supply Chain Defendants identified manufactured, shipped, paid for and received payment for the drugs identified above, throughout the United States.

814. The RICO Supply Chain Defendants used the Internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the RICO Supply Chain Defendants made misrepresentations about their compliance with federal and state laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

815. At the same time, the RICO Supply Chain Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and their compliance with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

1 816. The RICO Supply Chain Defendants utilized the Internet and other electronic
2 resources to exchange communications, to exchange information regarding prescription opioid sales,
3 and to transmit payments and rebates/chargebacks.

4 817. The RICO Supply Chain Defendants also communicated by U.S. Mail, by interstate
5 facsimile, and by interstate electronic mail with each other and with various other affiliates, regional
6 offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

7 818. The mail and wire transmissions described herein were made in furtherance of the
8 RICO Supply Chain Defendants' scheme and common course of conduct to deceive regulators, the
9 public and San Francisco into believing that they were complying with their state and federal
10 obligations to identify and report suspicious orders of prescription opioids, all while Defendants
11 were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug
12 market. The purpose of the RICO Supply Chain Defendants' scheme and common course of
13 conduct was to increase or maintain high production quotas for their prescription opioids from which
14 they could profit.

15 819. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire
16 facilities have been deliberately hidden by the RICO Supply Chain Defendants and cannot be alleged
17 without access to their books and records. However, San Francisco has described the types of, and
18 in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They
19 include thousands of communications to perpetuate and maintain the scheme, including the things
20 and documents described in the preceding paragraphs.

21 820. The RICO Supply Chain Defendants did not undertake the practices described herein
22 in isolation, but as part of a common scheme. Various other persons, firms, and corporations,
23 including third-party entities and individuals not named as defendants in this complaint, may have
24 contributed to and/or participated in the scheme with these defendants in these offenses and have
25

1 performed acts in furtherance of the scheme to increase revenues, increase market share, and /or
2 minimize the losses for the RICO Supply Chain Defendants.

3 821. The predicate acts constituted a variety of unlawful activities, each conducted with
4 the common purpose of obtaining significant monies and revenues from the sale of their highly
5 addictive and dangerous drugs. The predicate acts also had the same or similar results, participants,
6 victims, and methods of commission. The predicate acts were related and not isolated events.
7

8 822. The predicate acts all had the purpose of creating the opioid epidemic that
9 substantially injured San Francisco's business and property, while simultaneously generating billion-
10 dollar revenues and profits for the RICO Supply Chain Defendants. The predicate acts were
11 committed or caused to be committed by the RICO Supply Chain Defendants through their
12 participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.
13

14 823. As described above, the RICO Supply Chain Defendants were repeatedly warned,
15 fined, and found to be in violation of applicable law and regulations, and yet they persisted. The
16 sheer volume of enforcement actions against the RICO Supply Chain Defendants supports this
17 conclusion that the RICO Supply Chain Defendants operated through a pattern and practice of
18 willfully and intentionally omitting information from their mandatory reports to the DEA as required
19 by 21 C.F.R. §1301.74.
20

21 824. Each instance of racketeering activity alleged herein was related, had similar
22 purposes, involved the same or similar participants and methods of commission, and had similar
23 results affecting similar victims, including San Francisco. The RICO Supply Chain Defendants
24 calculated and intentionally crafted the diversion scheme to increase and maintain profits from
25 unlawful sales of opioids, without regard to the effect such behavior would have on San Francisco.
26 The RICO Supply Chain Defendants were aware that San Francisco relies on them to maintain a
27
28

1 closed system of manufacturing and distribution to protect against the non-medical diversion and use
2 of their dangerously addictive opioid drugs.

3 825. By intentionally refusing to report and halt suspicious orders of their prescription
4 opioids, the RICO Supply Chain Defendants engaged in a fraudulent scheme and unlawful course of
5 conduct constituting a pattern of racketeering activity.
6

7 **COUNT I – BY THE CITY AND COUNTY OF SAN FRANCISCO**

8 **Violation of RICO, 18 U.S.C. §1961 *et seq.* – Opioid Marketing Enterprise**
9 **(Against Defendants Purdue, Cephalon, Janssen, Endo, and Mallinckrodt**
10 **(the “RICO Marketing Defendants”))**

11 826. San Francisco repeats, realleges, and incorporates by reference each and every
12 allegation set forth above as if fully set forth herein.

13 827. At all relevant times, the RICO Marketing Defendants were and are “persons” under
14 18 U.S.C. §1961(3) because they are entities capable of holding, and do hold, “a legal or beneficial
15 interest in property.”

16 828. The RICO Marketing Defendants – through the use of Front Groups that appeared to
17 be independent of the RICO Marketing Defendants; through the dissemination of publications that
18 supported the RICO Marketing Defendants’ scheme; through CME programs controlled and/or
19 funded by the RICO Marketing Defendants; by the hiring and deployment of so-called “key opinion
20 leaders” (“KOLs”) who were paid by the RICO Marketing Defendants to promote their message;
21 and through the “detailing” activities of the RICO Marketing Defendants’ sales forces – conducted
22 an association-in-fact enterprise, and/or participated in the conduct of an enterprise through a pattern
23 of illegal activities (the predicate racketeering acts of mail and wire fraud) to carry out the common
24 purpose of the Opioid Marketing Enterprise, *i.e.*, to unlawfully increase profits and revenues from
25 the continued prescription and use of opioids for long-term chronic pain. Through the racketeering
26 activities of the Opioid Marketing Enterprise, the Rico Marketing Defendants sought to further the
27 common purpose of the enterprise through a fraudulent scheme to change prescriber habits and
28

1ST AMENDED CPT FOR: (1) RICO; (2) PUBLIC NUISANCE; (3) CALIF UCL; AND (4) FALSE

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1 public perception about the safety and efficacy of opioid use by convincing them that each of the
2 nine false propositions alleged earlier were true. In so doing, each of the RICO Marketing
3 Defendants knowingly conducted and participated in the conduct of the Opioid Marketing Enterprise
4 by engaging in mail and wire fraud in violation of 18 U.S.C. §§1962(c) and (d).

5
6 829. The Opioid Marketing Enterprise alleged above is an association-in-fact enterprise
7 that consists of the RICO Marketing Defendants (Purdue, Cephalon, Janssen, Endo, and
8 Mallinckrodt); the Front Groups (APF, AAPM, APS, FSMB, USPF, and AGS); and the KOLs
9 (Dr. Portenoy, Dr. Webster, Dr. Fine, and Dr. Fishman).

10 830. Each of the RICO Marketing Defendants and the other members of the Opioid
11 Marketing Enterprise conducted and participated in the conduct of the Opioid Marketing Enterprise
12 by playing a distinct role in furthering the enterprise's common purpose of increasing profits and
13 sales through the knowing and intentional dissemination of false and misleading information about
14 the safety and efficacy of long-term opioid use and the risks and symptoms of addiction, in order
15 increase the market for prescription opioids by changing prescriber habits and public perceptions and
16 increase the market for opioids.

17
18 831. Specifically, the RICO Marketing Defendants each worked together to coordinate the
19 enterprise's goals and conceal their role, and the enterprise's existence, from the public by, among
20 other things: (i) funding, editing and distributing publications that supported and advanced their false
21 messages; (ii) funding KOLs to further promote their false messages; (iii) funding, editing and
22 distributing CME programs to advance their false messages; and (iv) tasking their own employees to
23 direct deceptive marketing materials and pitches directly at physicians and, in particular, at
24 physicians lacking the expertise of pain care specialists (a practice known as sales detailing).

25
26 832. Each of the Front Groups helped disguise the role of RICO Marketing Defendants by
27 purporting to be unbiased, independent patient-advocacy and professional organizations in order to
28

1 disseminate patient education materials, a body of biased and unsupported scientific “literature,” and
2 “treatment guidelines” that promoted the RICO Marketing Defendants’ false messages.

3 833. Each of the KOLs were physicians chosen and paid by each of the RICO Marketing
4 Defendants to influence their peers’ medical practice by promoting the RICO Marketing Defendants’
5 false message through, among other things, writing favorable journal articles and delivering
6 supportive CMEs as if they were independent medical professionals, thereby further obscuring the
7 RICO Marketing Defendants’ role in the enterprise and the enterprise’s existence.

8
9 834. Further, each of the RICO Marketing Defendants, KOLs and Front Groups that made-
10 up the Opioid Marketing Enterprise had systematic links to and personal relationships with each
11 other through joint participation in lobbying groups, trade industry organizations, contractual
12 relationships and continuing coordination of activities. The systematic links and personal
13 relationships that were formed and developed allowed members of the Opioid Marketing Enterprise
14 the opportunity to form the common purpose and agree to conduct and participate in the conduct of
15 the Opioid Marketing Enterprise. Specifically, each of the RICO Marketing Defendants coordinated
16 their efforts through the same KOLs and Front Groups, based on their agreement and understanding
17 that the Front Groups and KOLs were industry friendly and would work together with the RICO
18 Marketing Defendants to advance the common purpose of the Opioid Marketing Enterprise; each of
19 the individuals and entities who formed the Opioid Marketing Enterprise acted to enable the
20 common purpose and fraudulent scheme of the Opioid Marketing Enterprise.

21
22
23 835. At all relevant times, the Opioid Marketing Enterprise: (a) had an existence separate
24 and distinct from each RICO Marketing Defendant and its members; (b) was separate and distinct
25 from the pattern of racketeering in which the RICO Marketing Defendants engaged; (c) was an
26 ongoing and continuing organization consisting of individuals, persons, and legal entities, including
27 each of the RICO Marketing Defendants; (d) was characterized by interpersonal relationships
28

1 between and among each member of the Opioid Marketing Enterprise, including between the RICO
2 Marketing Defendants and each of the Front Groups and KOLs; and (e) had sufficient longevity for
3 the enterprise to pursue its purpose and functioned as a continuing unit.

4 836. The persons and entities engaged in the Opioid Marketing Enterprise are
5 systematically linked through contractual relationships, financial ties, personal relationships, and
6 continuing coordination of activities, as spearheaded by the RICO Marketing Defendants.

7 837. The RICO Marketing Defendants conducted and participated in the conduct of the
8 Opioid Marketing Enterprise through a pattern of racketeering activity that employed the use of mail
9 and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud), to increase
10 profits and revenue by changing prescriber habits and public perceptions in order to increase the
11 prescription and use of prescription opioids, and expand the market for opioids.

12 838. The RICO Marketing Defendants each committed, conspired to commit, and/or aided
13 and abetted in the commission of at least two predicate acts of racketeering activity (*i.e.*, violations
14 of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity
15 that the RICO Marketing Defendants committed, or aided and abetted in the commission of, were
16 related to each other, posed a threat of continued racketeering activity, and therefore constitute a
17 “pattern of racketeering activity.” The racketeering activity was made possible by the RICO
18 Marketing Defendants’ regular use of the facilities, services, distribution channels, and employees of
19 the Opioid Marketing Enterprise, the U.S. Mail and interstate wire facilities. The RICO Marketing
20 Defendants participated in the scheme to defraud by using mail, telephones and the Internet to
21 transmit mailings and wires in interstate or foreign commerce.

22 839. The RICO Marketing Defendants’ predicate acts of racketeering (18 U.S.C. § 1961(1))
23 include, but are not limited to:
24

1 (a) Mail Fraud: The RICO Marketing Defendants violated 18 U.S.C. §1341 by
2 sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial
3 interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market,
4 and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and
5 omissions.

6 (b) Wire Fraud: The RICO Marketing Defendants violated 18 U.S.C. §1343 by
7 transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for
8 the purpose of executing the unlawful scheme to design, manufacture, market, and sell the
9 prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.
10

11 840. Indeed, as summarized herein, the RICO Marketing Defendants used the mail and
12 wires to send or receive thousands of communications, publications, representations, statements,
13 electronic transmissions and payments to carry out the Opioid Marketing Enterprise's fraudulent
14 scheme.
15

16 841. Because the RICO Marketing Defendants disguised their participation in the
17 enterprise, and worked to keep even the enterprise's existence secret so as to give the false
18 appearance that their false messages reflected the views of independent third parties, many of the
19 precise dates of the Opioid Marketing Enterprise's uses of the U.S. Mail and interstate wire facilities
20 (and corresponding predicate acts of mail and wire fraud) have been hidden and cannot be alleged
21 without access to the books and records maintained by the RICO Marketing Defendants, Front
22 Groups, and KOLs. Indeed, an essential part of the successful operation of the Opioid Marketing
23 Enterprise alleged herein depended upon secrecy. However, the RICO Marketing Defendants, Front
24 Groups, and KOLs disseminated misrepresentations and false statements to San Francisco, and to
25 consumers, prescribers, and regulators in San Francisco, and how those acts were in furtherance of
26 the scheme.
27
28

1 842. Each instance of racketeering activity alleged herein was related, had similar
2 purposes, involved the same or similar participants and methods of commission, and had similar
3 results affecting similar victims, including San Francisco, and consumers, prescribers, and regulators
4 in San Francisco. The RICO Marketing Defendants, Front Groups and KOLs calculated and
5 intentionally crafted the scheme and common purpose of the Opioid Marketing Enterprise to ensure
6 their own profits remained high. In designing and implementing the scheme, the RICO Marketing
7 Defendants understood and intended that those in the distribution chain would rely on the integrity of
8 the pharmaceutical companies and ostensibly neutral third parties to provide objective and scientific
9 evidence regarding the RICO Marketing Defendants' products.

11 843. The RICO Marketing Defendants' pattern of racketeering activity alleged herein and
12 the Opioid Marketing Enterprise are separate and distinct from each other. Likewise, the RICO
13 Marketing Defendants are distinct from the Opioid Marketing Enterprise.

15 844. The pattern of racketeering activity alleged herein is continuing as of the date of this
16 complaint, and, upon information and belief, will continue into the future unless enjoined by this
17 Court.

18 845. The racketeering activities conducted by the RICO Marketing Defendants, Front
19 Groups and KOLs amounted to a common course of conduct, with a similar pattern and purpose,
20 intended to deceive San Francisco. Each separate use of the U.S. Mail and/or interstate wire
21 facilities employed by the RICO Marketing Defendants was related, had similar intended purposes,
22 involved similar participants and methods of execution, and had the same results affecting the same
23 victims, including San Francisco. The RICO Marketing Defendants have engaged in the pattern of
24 racketeering activity for the purpose of conducting the ongoing business affairs of the Opioid
25 Marketing Enterprise.
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1 846. Each of the RICO Marketing Defendants aided and abetted others in the violations of
2 the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§1341 and 1343
3 offenses.

4 847. As described herein, the RICO Marketing Defendants engaged in a pattern of related
5 and continuous predicate acts for years. The predicate acts constituted a variety of unlawful
6 activities, each conducted with the common purpose of obtaining significant money and revenue
7 from the marketing and sale of their highly addictive and dangerous drugs. The predicate acts also
8 had the same or similar results, participants, victims, and methods of commission. The predicate
9 acts were related and not isolated events.
10

11 848. The pattern of racketeering activity alleged herein is continuing as of the date of this
12 complaint and, upon information and belief, will continue into the future unless enjoined by this
13 Court. The last racketeering incident occurred within five years of the commission of a prior
14 incident of racketeering.
15

16 849. The RICO Marketing Defendants' violations of law and their pattern of racketeering
17 activity directly and proximately caused San Francisco injury in its business and property. The
18 RICO Marketing Defendants' pattern of racketeering activity logically, substantially and foreseeably
19 caused an opioid epidemic. San Francisco's injuries, as described below, were not unexpected,
20 unforeseen or independent.²⁶¹ Rather, as San Francisco alleges, the RICO Marketing Defendants
21 knew that the opioids were unsuited to treatment of long-term chronic, non-acute, and non-cancer
22 pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and
23 subject to abuse.²⁶² Nevertheless, the RICO Marketing Defendants engaged in a scheme of
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25
26

27 ²⁶¹ *Travelers Prop. Cas. Co. of Am. v. Actavis, Inc.*, 16 Cal. App. 5th 1026, 1030 (2017).

28 ²⁶² *Id.* at 1041.

1 deception that utilized the mail and wires in order to carry out the Opioid Marketing Enterprise's
 2 fraudulent scheme, thereby increasing sales of their opioid products, including in San Francisco.

3 850. It was foreseeable and expected that the RICO Marketing Defendants creating and
 4 then participating in the Opioid Marketing Enterprise through a pattern of racketeering activities to
 5 carry out their fraudulent scheme would lead to a nationwide opioid epidemic, including increased
 6 opioid addiction and overdose in San Francisco.²⁶³

7
 8 851. Specifically, the RICO Marketing Defendants' creating and then participating in the
 9 Opioid Marketing Enterprise through a pattern of racketeering activities to carry out their fraudulent
 10 scheme has injured San Francisco in the form of substantial losses of money and property that
 11 logically, directly and foreseeably arise from the opioid epidemic. San Francisco's injuries, as
 12 alleged throughout this complaint, and expressly incorporated herein by reference, include, without
 13 limitation:

14
 15 (a) Losses caused by the decrease in funding available for San Francisco's public
 16 services for which funding was lost because it was diverted to other public services designed to
 17 address the opioid epidemic;

18 (b) Increased costs for providing healthcare and medical care, additional
 19 therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-
 20 related addiction or disease, including overdoses and deaths;

21
 22 (c) Increased costs of training emergency and/or first responders and other city
 23 employees in the proper treatment of drug overdoses;

24 (d) Increased costs associated with providing police officers, firefighters,
 25 emergency and/or first responders, and other city employees with naloxone – an opioid antagonist
 26 used to block the deadly effects of opioids in the context of overdose;

27
 28 ²⁶³ *Id.*

1 (e) Increased costs associated with emergency responses by police officers,
2 firefighters, emergency and/or first responders, and other city employees to opioid overdoses;

3 (f) Increased costs for providing mental-health services, treatment, counseling,
4 rehabilitation services, and social services to victims of the opioid epidemic and their families;

5 (g) Increased costs associated with the destruction of city property and public
6 infrastructure, including damages caused by improper needle and syringe disposal; and
7

8 (h) Increased costs associated with maintaining the city and county jail system,
9 including increased training and supplies for jail staff, as well as the purchase of specialized
10 screening equipment – at a cost of \$250,000 per unit – to detect opioids being sent into the jails.

11 852. San Francisco’s injuries were directly and proximately caused by the RICO
12 Marketing Defendants’ racketeering activities because they were the logical, substantial and
13 foreseeable cause of San Francisco’s injuries. But for the opioid-addiction epidemic the RICO
14 Marketing Defendants created through their Opioid Marketing Enterprise, San Francisco would not
15 have lost money or property. Such costs were either completely new or greatly in excess of the norm
16 of what San Francisco would ordinarily pay or be expected to pay to provide services to its residents.
17

18 853. San Francisco is the most directly harmed entity, and there is no other plaintiff better
19 suited to seek a remedy for the economic harms at issue here.
20

21 854. San Francisco seeks all legal and equitable relief as allowed by law, including, *inter*
22 *alia*, actual damages; treble damages; equitable and/or injunctive relief in the form of court-
23 supervised corrective communications, actions and programs; forfeiture as deemed proper by the
24 Court; attorney’s fees; all costs and expenses of suit; and pre- and post-judgment interest. With
25 respect to equitable and/or injunctive relief, San Francisco seeks, *inter alia*:

26 (a) An order enjoining any further violations of RICO;
27
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1 (b) An order enjoining any further violations of any statutes alleged to have been
2 violated in this complaint;

3 (c) An order enjoining the commission of any tortious or illegal conduct, as
4 alleged in this complaint;

5 (d) An order enjoining any future marketing or misrepresentations regarding the
6 health benefits or risks of prescription opioids use, except as specifically approved by the FDA;

7 (e) An order enjoining any future marketing of opioids through non-branded
8 marketing, including through the Front Groups, KOLs, websites, or in any other manner alleged in
9 this complaint that deviates from the manner or method in which such marketing has been approved
10 by the FDA;

11 (f) An order enjoining any future marketing to vulnerable populations, including
12 but not limited to, persons over the age of 55, anyone under the age of 21, and veterans;

13 (g) An order compelling the RICO Marketing Defendants to make corrective
14 advertising statements that shall be made in the form, manner and duration as determined by the
15 Court, but not less than print advertisements in national and regional newspapers and medical
16 journals, televised broadcast on major television networks, and displayed on their websites,
17 concerning: (1) the risk of addiction among patients taking opioids for pain; (2) the ability to
18 manage the risk of addiction; (3) pseudoaddiction is really addiction, not a sign of undertreated
19 addiction; (4) withdrawal from opioids is not easily managed; (5) increasing opioid dosing presents
20 significant risks, including addiction and overdose; (6) long-term use of opioids has no demonstrated
21 improvement of function; (8) use of time-released opioids does not prevent addiction; (9) abuse-
22 deterrent formulations do not prevent opioid abuse; and (10) that manufacturers and distributors have
23 duties under the CSA to monitor, identify, investigate, report and halt suspicious orders and
24 diversion but failed to do so;

1 (h) An order enjoining any future lobbying or legislative efforts regarding the
2 manufacture, marketing, distribution, diversion, prescription, or use of opioids;

3 (i) An order requiring the RICO Marketing Defendants to publicly disclose all
4 documents, communications, records, data, information, research or studies concerning the health
5 risks or benefits of opioid use;

6 (j) An order prohibiting the RICO Marketing Defendants from entering into any
7 new payment or sponsorship agreement with, or related to, any: Front Group, trade association,
8 doctor, speaker, CME, or any other person, entity, or association, regarding the manufacturer,
9 marketing, distribution, diversion, prescription, or use of opioids;

10 (k) An order establishing a national foundation for education, research,
11 publication, scholarship, and dissemination of information regarding the health risks of opioid use
12 and abuse to be financed by the RICO Marketing Defendants in an amount to be determined by the
13 Court;

14 (l) An order divesting the RICO Marketing Defendants of any interest in, and the
15 proceeds of any interest in, the Opioid Marketing Enterprise, including any interest in property
16 associated with the Opioid Marketing Enterprise;

17 (m) Dissolution and/or reorganization of any trade industry organization, Front
18 Group, or any other entity or association associated with the Opioid Marketing Enterprise identified
19 in this complaint, as the Court sees fit;

20 (n) Dissolution and/or reorganization of any RICO Marketing Defendant named
21 in this complaint as the Court sees fit; and

22 (o) Suspension and/or revocation of the license, registration, permit, or prior
23 approval granted to any RICO Marketing Defendant, entity, association or enterprise named in the
24 complaint regarding the marketing of opioids.

COUNT II – BY THE CITY AND COUNTY OF SAN FRANCISCO

**Violation of RICO, 18 U.S.C. §1961 *et seq.* – Opioid Supply Chain Enterprise
(Against Defendants Purdue, Cephalon, Endo, Mallinckrodt,
Actavis, Mckesson, Cardinal, Anda, and AmerisourceBergen
(the “RICO Supply Chain Defendants”))**

855. San Francisco repeats, realleges, and incorporates by reference each and every allegation set forth above as if fully set forth herein.

856. At all relevant times, the RICO Supply Chain Defendants were and are “persons” under 18 U.S.C. §1961(3) because they are entities capable of holding, and do hold, “a legal or beneficial interest in property.”

857. The RICO Supply Chain Defendants together formed an association-in-fact enterprise, the Opioid Supply Chain Enterprise, for the purpose of increasing the quota for and profiting from the increased volume of opioid sales in the United States. The Opioid Supply Chain Enterprise is an association-in-fact enterprise within the meaning of §1961. The Opioid Supply Chain Enterprise consists of the RICO Supply Chain Defendants.

858. The RICO Supply Chain Defendants were members of the HDA.²⁶⁴ Each of the RICO Supply Chain Defendants is a member, participant, and/or sponsor of the HDA, and has been since at least 2006, and utilized the HDA to form the interpersonal relationships of the Opioid Supply Chain Enterprise and to assist them in engaging in the pattern of racketeering activity that gives rise to this Count.

859. At all relevant times, the Opioid Supply Chain Enterprise: (a) had an existence separate and distinct from each of the RICO Supply Chain Defendants; (b) was separate and distinct from the pattern of racketeering in which the RICO Supply Chain Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the RICO Supply

²⁶⁴ *History*, Health Distribution Alliance, <https://www.hda.org/about/hda-history> (last visited Mar. 13, 2020).

1 Chain Defendants; (d) was characterized by interpersonal relationships among the RICO Supply
2 Chain Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and
3 (f) functioned as a continuing unit. Each member of the Opioid Supply Chain Enterprise
4 participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in
5 the astounding growth of profits supplied by fraudulently inflating opioid quotas and resulting sales.
6

7 860. The RICO Supply Chain Defendants carried out, or attempted to carry out, a scheme
8 to defraud federal and state regulators, the American public, and San Francisco by knowingly
9 conducting or participating in the conduct of the Opioid Supply Chain Enterprise through a pattern
10 of racketeering activity within the meaning of 18 U.S.C. §1961(1) that employed the use of mail and
11 wire facilities, in violation of 18 U.S.C. §1341 (mail fraud) and §1343 (wire fraud).
12

13 861. The RICO Supply Chain Defendants committed, conspired to commit, and/or aided
14 and abetted in the commission of at least two predicate acts of racketeering activity (*e.g.*, violations
15 of 18 U.S.C. §§1341 and 1343) within the past ten years. The multiple acts of racketeering activity
16 that the RICO Supply Chain Defendants committed, or aided and abetted in the commission of, were
17 related to each other, posed a threat of continued racketeering activity, and therefore constitute a
18 “pattern of racketeering activity.” The racketeering activity was made possible by the RICO Supply
19 Chain Defendants’ regular use of the facilities, services, distribution channels, and employees of the
20 Opioid Supply Chain Enterprise. The RICO Supply Chain Defendants participated in the scheme to
21 defraud by using mail, telephone and the Internet to transmit mailings and wires in interstate or
22 foreign commerce.
23

24 862. The RICO Supply Chain Defendants also conducted and participated in the conduct
25 of the affairs of the Opioid Supply Chain Enterprise through a pattern of racketeering activity by the
26 felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in
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1 a controlled substance or listed chemical (as defined in §102 of the Controlled Substances Act),
2 punishable under the laws of the United States.

3 863. The RICO Supply Chain Defendants committed crimes that are punishable as felonies
4 under the laws of the United States. Specifically, 21 U.S.C. §843(a)(4) makes it unlawful for any
5 person to knowingly or intentionally furnish false or fraudulent information in, or omit any material
6 information from, any application, report, record or other document required to be made, kept or
7 filed under this subchapter. A violation of §843(a)(4) is punishable by up to four years in jail,
8 making it a felony. 21 U.S.C. §843(d)(1).

10 864. Each of the RICO Supply Chain Defendants is a registrant as defined in the CSA.
11 Their status as registrants under the CSA requires that they maintain effective controls against
12 diversion of controlled substances in Schedule I or II, design and operate a system to disclose to the
13 registrant suspicious orders of controlled substances, and inform the DEA of suspicious orders when
14 discovered by the registrant. 21 U.S.C. §823; 21 C.F.R. §1301.74(b).

16 865. The RICO Supply Chain Defendants' predicate acts of racketeering (18 U.S.C.
17 §1961(1)) include, but are not limited to:

18 (a) Mail Fraud: The RICO Supply Chain Defendants violated 18 U.S.C. §1341 by
19 sending or receiving, or by causing to be sent and/or received, materials via U.S. Mail or commercial
20 interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market,
21 and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and
22 omissions.

24 (b) Wire Fraud: The RICO Supply Chain Defendants violated 18 U.S.C. §1343 by
25 transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for
26 the purpose of executing the unlawful scheme to design, manufacture, market, and sell the
27 prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

1 (c) CSA Violations: The RICO Supply Chain Defendants who are Distributor
2 Defendants violated 21 U.S.C. §823 by knowingly or intentionally furnishing false or fraudulent
3 information in, and/or omitting material information from, documents filed with the DEA.

4 866. The RICO Supply Chain Defendants conducted their pattern of racketeering activity
5 in this jurisdiction and throughout the United States through this enterprise.
6

7 867. The RICO Supply Chain Defendants aided and abetted others in the violations of the
8 above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§1341 and 1343
9 offenses.

10 868. The RICO Supply Chain Defendants hid from the general public and suppressed
11 and/or ignored warnings from third parties, whistleblowers, and governmental entities about the
12 reality of the suspicious orders that the RICO Supply Chain Defendants were filling on a daily basis
13 – leading to the diversion of hundreds of millions of doses of prescriptions opioids into the illicit
14 market, including in San Francisco.
15

16 869. The RICO Supply Chain Defendants, with knowledge and intent, agreed to the
17 overall objective of their fraudulent scheme and participated in the common course of conduct to
18 commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

19 870. Indeed, for the RICO Supply Chain Defendants' fraudulent scheme to work, each of
20 them had to agree to implement similar tactics regarding manufacturing prescription opioids and
21 refusing to report suspicious orders.
22

23 871. As described herein, the RICO Supply Chain Defendants engaged in a pattern of
24 related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful
25 activities, each conducted with the common purpose of obtaining significant monies and revenues
26 from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or
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1 similar results, participants, victims, and methods of commission. The predicate acts were related
2 and not isolated events.

3 872. The predicate acts all had the purpose of creating the opioid epidemic that
4 substantially injured San Francisco's business and property, while simultaneously generating billion-
5 dollar revenues and profits for the RICO Supply Chain Defendants. The predicate acts were
6 committed or caused to be committed by the RICO Supply Chain Defendants through their
7 participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.
8

9 873. The pattern of racketeering activity alleged herein and the Opioid Supply Chain
10 Enterprise are separate and distinct from each other. Likewise, the RICO Supply Chain Defendants
11 are distinct from the enterprise.

12 874. The pattern of racketeering activity alleged herein is continuing as of the date of this
13 complaint and, upon information and belief, will continue into the future unless enjoined by this
14 Court.
15

16 875. Many of the precise dates of the RICO Supply Chain Defendants' criminal actions at
17 issue here have been hidden by the RICO Supply Chain Defendants and cannot be alleged without
18 access to their books and records. Indeed, an essential part of the successful operation of the Opioid
19 Supply Chain Enterprise alleged herein depended upon secrecy.
20

21 876. By intentionally refusing to report and halt suspicious orders of their prescription
22 opioids, the RICO Supply Chain Defendants engaged in a fraudulent scheme and unlawful course of
23 conduct constituting a pattern of racketeering activity.

24 877. It was foreseeable to the RICO Supply Chain Defendants that San Francisco would be
25 harmed when they refused to report and halt suspicious orders, because their violation of the duties
26 imposed by the CSA and Code of Federal Regulations allowed the widespread diversion of
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1 prescription opioids out of appropriate medical channels and into the illicit drug market, including in
2 San Francisco – causing the opioid epidemic that the CSA intended to prevent.

3 878. The last racketeering incident occurred within five years of the commission of a prior
4 incident of racketeering.

5 879. The RICO Supply Chain Defendants’ violations of law and their pattern of
6 racketeering activity directly and proximately caused San Francisco injury in its business and
7 property. The RICO Supply Chain Defendants’ pattern of racketeering activity, including their
8 refusal to identify, report and halt suspicious orders of controlled substances, logically, substantially
9 and foreseeably caused an opioid epidemic. San Francisco was injured by the RICO Supply Chain
10 Defendants’ pattern of racketeering activity and the opioid epidemic that they created.

11 880. The RICO Supply Chain Defendants knew that the opioids they manufactured and
12 supplied were unsuited to treatment of long-term chronic, non-acute, and non-cancer pain, or for any
13 other use not approved by the FDA, and knew that opioids were highly addictive and subject to
14 abuse.²⁶⁵ Nevertheless, the RICO Supply Chain Defendants engaged in a scheme of deception that
15 utilized the mail and wires as part of their fraud, in order to increase sales of their opioid products by
16 refusing to identify and report suspicious orders of prescription opioids that they knew were highly
17 addictive, subject to abuse, and were actually being diverted into the illegal market.²⁶⁶

18 881. The RICO Supply Chain Defendants’ predicate acts and pattern of racketeering
19 activity were a cause of the opioid epidemic that has injured San Francisco in the form of substantial
20 losses of money and property that logically, directly and foreseeably arise from the opioid-addiction
21 epidemic.

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26 ²⁶⁵ *Travelers Prop.*, 16 Cal. App. 5th at 1030.

27 ²⁶⁶ *City of Everett v. Purdue Pharma L.P.*, Case No. 17-cv-00209, 2017 WL 4236062, *2 (W.D.
28 Wash. Sept. 25, 2017).

1 882. Specifically, San Francisco's injuries, as alleged throughout this complaint, and
2 expressly incorporated herein by reference, include:

3 (a) Losses caused by the decrease in funding available for San Francisco's public
4 services for which funding was lost because it was diverted to other public services designed to
5 address the opioid epidemic;

6 (b) Increased costs for providing healthcare and medical care, additional
7 therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-
8 related addiction or disease, including overdoses and deaths;

9 (c) Increased costs of training emergency and/or first responders and other city
10 employees in the proper treatment of drug overdoses;

11 (d) Increased costs associated with providing police officers, firefighters,
12 emergency and/or first responders and other city employees with naloxone – an opioid antagonist
13 used to block the deadly effects of opioids in the context of overdose;

14 (e) Increased costs associated with emergency responses by police officers,
15 firefighters, emergency and/or first responders, and other city employees to opioid overdoses;

16 (f) Increased costs for providing mental-health services, treatment, counseling,
17 rehabilitation services, and social services to victims of the opioid epidemic and their families;

18 (g) Increased costs associated with the destruction of city property and public
19 infrastructure, including damages caused by improper needle and syringe disposal; and

20 (h) Increased costs associated with maintaining the city and county jail system,
21 including increased training and supplies for jail staff, as well as the purchase of specialized
22 screening equipment – at a cost of \$250,000 per unit – to detect opioids being sent into the jails.

23 883. San Francisco's injuries were directly and proximately caused by the RICO Supply
24 Chain Defendants' racketeering activities because they were the logical, substantial and foreseeable
25

1 cause of San Francisco's injuries. But for the opioid-addiction epidemic created by the RICO
 2 Supply Chain Defendants' conduct, San Francisco would not have lost money or property. Such
 3 costs were either completely new or greatly in excess of the norm of what San Francisco would
 4 ordinarily pay or be expected to pay to provide services to its residents.

5 884. San Francisco is the most directly harmed entity, and there is no other plaintiff better
 6 suited to seek a remedy for the economic harms at issue here.

7 885. San Francisco seeks all legal and equitable relief as allowed by law, including, *inter*
 8 *alia*, actual damages; treble damages; equitable and/or injunctive relief in the form of court-
 9 supervised corrective communications, actions and programs; forfeiture as deemed proper by the
 10 Court; attorney's fees; all costs and expenses of suit; and pre- and post-judgment interest. With
 11 respect to equitable and/or injunctive relief, San Francisco seeks, *inter alia*:
 12

13 (a) An order enjoining any further violations of RICO;

14 (b) An order enjoining any further violations of any statutes alleged to have been
 15 violated in this complaint;

16 (c) An order enjoining the commission of any further misconduct, as alleged in
 17 this complaint;

18 (d) An order enjoining any future marketing to vulnerable populations, including
 19 but not limited to, persons over the age of 55, anyone under the age of 21, and veterans;

20 (e) An order enjoining any future lobbying or legislative efforts regarding the
 21 manufacture, marketing, distribution, diversion, prescription, or use of opioids;

22 (f) An order requiring all RICO Supply Chain Defendants to publicly disclose all
 23 documents, communications, records, data, information, research or studies concerning the health
 24 risks or benefits of opioid use;
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(g) An order establishing a national foundation for education, research, publication, scholarship, and dissemination of information regarding the health risks of opioid use and abuse to be financed by the RICO Supply Chain Defendants in an amount to be determined by the Court;

(h) An order enjoining any diversion of opioids or any failure to monitor, identify, investigate, report and halt suspicious orders or diversion of opioids;

(i) An order requiring all RICO Supply Chain Defendants to publicly disclose all documents, communications, records, information, or data, regarding any prescriber, facility, pharmacy, clinic, hospital, manufacturer, distributor, person, entity or association regarding suspicious orders for or the diversion of opioids;

(j) An order divesting each RICO Supply Chain Defendant of any interest in, and the proceeds of any interest in, the Opioid Supply Chain Enterprise, including any interest in property associated with the Opioid Supply Chain Enterprise;

(k) Dissolution and/or reorganization of any trade industry organization, Front Group, or any other entity or association associated with the Opioid Supply Chain Enterprise identified in this complaint, as the Court sees fit;

(l) Dissolution and/or reorganization of any RICO Supply Chain Defendant named in this complaint as the Court sees fit; and

(m) Suspension and/or revocation of the license, registration, permit, or prior approval granted to any RICO Supply Chain Defendant, entity, association or enterprise named in the complaint regarding the distribution of opioids.

COUNT III – BY THE PEOPLE OF THE STATE OF CALIFORNIA

Public Nuisance in San Francisco Violations of California Civil Code §§3479-3480 (Against All Defendants)

886. The People incorporate herein by reference all the allegations of this complaint. 1ST AMENDED CPT FOR: (1) RICO; (2) PUBLIC NUISANCE; (3) CALIF UCL; AND (4) FALSE ADVERTISING LAW – CASE NO. 3:18-cv-07591-CRB

1 887. California Civil Code §3479 provides that “[a]nything which is injurious to health . . .
2 or is indecent or offensive to the senses, or an obstruction to the free use of property, so as to
3 interfere with the comfortable enjoyment of life or property . . . is a nuisance.”

4 888. California Civil Code §3480 defines a “public nuisance” as “one which affects at the
5 same time an entire community or neighborhood, or any considerable number of persons, although
6 the extent of the annoyance or damage inflicted upon individuals may be unequal.”

7 889. California Code of Civil Procedure §731 authorizes the “city attorney of any . . . city
8 in which the nuisance exists” to bring a “civil action . . . in the name of the people of the State of
9 California to abate a public nuisance.” The law only permits a city attorney to bring a civil action to
10 abate a public nuisance that exists within the city attorney’s geographical jurisdiction.

11 890. A public nuisance cause of action is established where a defendant knowingly created
12 or assisted in the creation of a substantial and unreasonable interference with a public right.
13

14 891. California Civil Code §3490 states that “[n]o lapse of time can legalize a public
15 nuisance, amounting to an actual obstruction of public right.”
16

17 892. Each of the Marketing Defendants acted in a way injurious to the public health and
18 interfered with the comfortable enjoyment of life and property of San Francisco’s residents by,
19 among other things, promoting and marketing the use of prescription opioids for indications not
20 federally approved, circulating false and misleading information concerning prescription opioids’
21 safety and efficacy, and/or downplaying or omitting the risk of addiction and overdose arising from
22 the use of prescription opioids. In so doing, each of the Marketing Defendants acted with
23 oppression, fraud or malice.
24

25 893. Each of the Defendants unreasonably interfered with the public health, safety, peace
26 and comfort of San Francisco’s residents by failing to design and operate a system that would
27 disclose the existence of suspicious orders of controlled substances and/or by failing to report and
28

1 stop shipment of suspicious orders of opioids, as required by the CSA, 21 C.F.R. §1301.74(b), and
2 California Business & Professions Code §§4301 and 4164. In so doing, each of the Defendants
3 acted with oppression, fraud or malice.

4 894. Defendant Walgreens also unreasonably interfered with the public health, safety
5 peace, and comfort of San Francisco's residents by failing to ensure that it dispensed only legitimate
6 opioid prescriptions and failing to implement effective controls and procedures to prevent diversion.
7 See 21 C.F.R. §§1301.71(a), 1306.04(a). In so doing, Walgreens acted with oppression, fraud or
8 malice.
9

10 895. Defendants are persons who have violated, and/or who have aided and abetted the
11 violation of, the laws of California and/or of the United States of America or of any rule of the board
12 of pharmacy controlling the distribution of a controlled substance as defined in California Health &
13 Safety Code §11007.
14

15 896. The Distributor Defendants' conduct includes the clearly excessive furnishing of
16 controlled substances in violation of the Cal. Health & Safety Code §11153.5(a) and Cal. Bus. &
17 Prof. Code §4301(d).

18 897. Defendant Walgreens' conduct includes the filling of prescriptions in the presence of
19 factors questioning the legitimacy of the prescription or the prescriber in violation of 21 C.F.R.
20 §1306.04.
21

22 898. Defendants' unlawful conduct includes violating and/or aiding and abetting the
23 violation of federal and California statutes and regulations, including the controlled substances laws,
24 by, *inter alia*:

25 (a) Distributing and selling opioids in ways that facilitated and encouraged their
26 flow into the illegal, secondary market;
27
28

1 (b) Distributing and selling opioids without maintaining effective controls against
2 the diversion of opioids; and

3 (c) Choosing not to stop or suspend shipments of suspicious orders.

4 899. Defendants' conduct created an ongoing, significant, unlawful, and unreasonable
5 interference with the public health, welfare, safety, peace, comfort, and convenience of the San
6 Francisco community.

7
8 900. Defendants had control over their conduct in San Francisco and that conduct has had
9 an adverse effect on the public right. The Marketing Defendants controlled their deceptive
10 advertising and efforts to mislead the public, including their acts and omissions in detailing by their
11 sales representatives, online communications, publications, CME programs and other speaking
12 events, and by other means described in this complaint. Defendants had control over their own
13 shipments and/or prescriptions of opioids and over their monitoring and reporting, or lack thereof, of
14 suspicious prescribers and orders. Each of the Defendants controlled the systems they developed to
15 ostensibly prevent diversion, including whether they filled orders they knew or should have known
16 were likely to be diverted or fuel an illegal market.

17
18 901. The nuisance created by Defendants' conduct is abatable.

19 902. The People, seeking to abate harms that have occurred in San Francisco, allege
20 wrongful acts that are neither discrete nor of the sort a local government can reasonably expect.

21
22 903. The unlawful conduct of each of the Defendants was a substantial factor in producing
23 harm to the People, who, in this lawsuit, seek to abate harms that have occurred in San Francisco.

24 904. As detailed herein, Defendants' conduct has interfered, and continues to interfere,
25 with rights common to the general public of San Francisco and has caused its residents to sustain
26 injury.

1 905. The People seek costs that will be associated with future efforts to abate the public
2 nuisance in San Francisco caused in whole or in part by Defendants, as well as injunctive relief to
3 lessen or prevent the threat of future harm from Defendants' actions.

4 906. The People seek all other legal and equitable relief as allowed by law.

5 **COUNT IV – BY THE PEOPLE OF THE STATE OF CALIFORNIA**

6 **Violation of California Unfair Competition Law**
7 **Cal. Bus. & Prof. Code §17200 *et seq.***
8 **(Against All Defendants Except Walgreens)**

9 907. The People incorporate herein by reference all of the allegations in this complaint.

10 908. The California Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code §17200
11 *et seq.*, prohibits "any unlawful, unfair or fraudulent business act or practice and unfair, deceptive,
12 untrue or misleading advertising and any act prohibited by" Cal. Bus. & Prof. Code §17500. Section
13 17500, in turn, prohibits any untrue or misleading statements made in connection with the sale of
14 goods and services. The Consumers Legal Remedies Act ("CLRA") defines as statutorily unlawful
15 certain unfair methods of competition and unfair or deceptive practices. Cal. Civ. Code §1750
16 *et seq.*

17 909. San Francisco City Attorney Dennis J. Herrera has standing to prosecute this claim in
18 the name of the People of the State of California under Cal. Bus. & Prof. Code §17204 and brings
19 this claim on behalf of the People for violations occurring within San Francisco.²⁶⁷

20 910. During the relevant period and as detailed herein, Defendants have each engaged in
21 unlawful, unfair and fraudulent business acts and practices in violation of the UCL, including, but
22 not limited to, making untrue and misleading statements in connection with the sale of goods as
23 prohibited by Cal. Bus. & Prof. Code §17500 and certain unfair methods of competition and unfair
24 or deceptive acts prohibited by the CLRA and UCL.
25
26

27 ²⁶⁷ San Francisco City Attorney Dennis J. Herrera is empowered to pursue remedies for UCL
28 violations on a statewide basis but chooses not to do so here.

1 911. Each of the Marketing Defendants circulated false and misleading information
2 concerning, among other things, the safety and efficacy of its prescription opioids and/or prescription
3 opioids generally, and falsely and misleadingly downplayed or omitted the risk of addiction arising
4 from their use. In addition, each of the Marketing Defendants represented that its prescription
5 opioids and/or prescription opioids in general had characteristics, uses and benefits that they did not
6 have, and disparaged other medications, including NSAIDs, by false and misleading representations
7 of fact.
8

9 912. Each Defendant named herein unlawfully violated the CSA and engaged in fraudulent
10 and unfair practices by failing to design and operate a system to monitor suspicious orders of
11 controlled substances, and failed to disclose such suspicious orders, as required of “registrant[s]” by
12 the federal CSA, 21 C.F.R. §1301.74(b), and Cal. Bus. & Prof. Code §§4301 and 4164. The CSA
13 defines “registrant” as any person who is registered pursuant to 21 U.S.C. §823. 21 C.F.R.
14 §1300.02(b). Sections 823(a) and (b) require manufacturers and distributors of controlled substances
15 on Schedule II, including each of the Defendants, to register. In addition, each defendant named
16 herein failed to report all sales of dangerous drugs subject to abuse pursuant to Cal. Code Regs. tit.
17 16, §1782.
18

19 913. Each of the Distributor Defendants (except Walgreens) failed to notify the California
20 State Board of Pharmacy in writing of suspicious orders of controlled substances, as required by Cal.
21 Bus. & Prof. Code §4169.1.
22

23 914. Defendants’ acts, omissions, and misrepresentations as alleged herein were unlawful
24 business practices and acts in violation of, *inter alia*, the CLRA; Cal. Bus. & Prof. Code §17500 *et*
25 *seq.*; RICO; the federal CSA; Cal. Code Regs. tit. 16, §1782; and Cal. Bus. & Prof. Code §4169.1.
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1 915. Each Defendant unfairly participated in the oversupply of opioids to San Franciscans
 2 by: (i) promoting their use in a manner that minimized serious risks; (ii) improperly touting
 3 purported benefits; and/or (iii) failing to make reasonable efforts to prevent diversion.

4 916. The harm caused by Defendants' actions, misrepresentations, and omissions, as
 5 described in detail throughout, greatly outweigh any perceived utility.

6 917. Defendants' actions, misrepresentations, and omissions, as described in detail
 7 throughout, violated fundamental public policies.

8 918. Each of these Defendants' unlawful, unfair and deceptive acts or practices in violation
 9 of the UCL, CLRA, and CSA offend California's public policy, are immoral, unethical, oppressive
 10 or unscrupulous, are malicious, wanton and manifest ill will and caused substantial injury to San
 11 Francisco and its residents.

12 919. As a direct and proximate result of the foregoing acts and practices, each of these
 13 Defendants received income, profits and other benefits that they would not have received if they had
 14 not engaged in UCL violations. The People seek injunctive relief, restitution and civil penalties for
 15 violations occurring within San Francisco as permitted by law for these Defendants' UCL violations.

16 **COUNT V – BY THE PEOPLE OF THE STATE OF CALIFORNIA**

17 **Violation of False Advertising Law** **Cal. Bus. & Prof. Code §17500 *et seq.*** **(Against the Marketing Defendants)**

18 920. The People incorporate herein by reference all of the allegations in this complaint.

19 921. The False Advertising Law, Cal. Bus. & Prof. Code §17500 *et seq.* makes it unlawful
 20 for any corporation or employee thereof to make or disseminate, or cause to be made or
 21 disseminated, any untrue or misleading statement in connection with the sale of any good or service,
 22 when it was known or could have been known by the exercise of reasonable care to be untrue or
 23 misleading.

1 922. San Francisco City Attorney Dennis J. Herrera has standing to prosecute this claim in
 2 the name of the People of the State of California under Cal. Bus. & Prof. Code §17535 and brings
 3 this claim on behalf of the People for violations occurring within San Francisco.²⁶⁸

4 923. During the relevant period and as detailed herein, each of the Marketing Defendants
 5 engaged in unlawful, unfair and fraudulent business acts and practices in violation of the False
 6 Advertising Law by making untrue and misleading statements in connection with the sale of goods.
 7 Each Marketing Defendant circulated false and misleading information concerning, among other
 8 things, the safety and efficacy of its prescription opioids and/or prescription opioids generally, and
 9 falsely and misleadingly downplayed or omitted the risk of addiction arising from their use. In
 10 addition, each Marketing Defendant represented that its prescription opioids and/or prescription
 11 opioids in general had characteristics, uses and benefits that they did not have, and disparaged other
 12 medications, including NSAIDs, by false and misleading representations of fact.
 13
 14

15 924. Each of the Marketing Defendants' misrepresentations and omissions in connection
 16 with the sale of prescription opioids offend California's public policy, are immoral, unethical,
 17 oppressive or unscrupulous, are malicious, wanton and manifest ill will and caused substantial injury
 18 to San Francisco and its residents.

19 925. As a direct and proximate result of the foregoing acts and practices, each of these
 20 defendants received income, profits and other benefits that they would not have received if they had
 21 not engaged in violations of the False Advertising Law. The People seek injunctive relief, restitution
 22 and civil penalties for violations occurring within San Francisco as permitted by law for the
 23 Marketing Defendants' violations of the False Advertising Law.
 24
 25
 26

27 ²⁶⁸ San Francisco City Attorney Dennis J. Herrera is empowered to pursue remedies for FAL
 28 violations on a statewide basis but chooses not to do so here.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter an order of judgment granting all relief requested in this complaint, and/or allowed at law or in equity, including:

- A. abatement of the nuisance;
- B. actual damages;
- C. treble or multiple damages and civil penalties as allowed by statute;
- D. equitable and injunctive relief in the form of Court-enforced corrective action, programs, and communications;
- E. attorneys' fees;
- F. costs and expenses of suit;
- G. pre- and post-judgment interest; and
- H. such other and further relief as this Court deems appropriate.

JURY DEMAND

Plaintiffs hereby demand trial by jury on all claims so triable.

DATED: March 13, 2020

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I hereby certify under penalty of perjury that on March 13, 2020, I authorized the electronic filing of the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the e-mail addresses on the attached Electronic Mail Notice List, and I hereby certify that I caused the mailing of the foregoing via the United States Postal Service to the non-CM/ECF participants indicated on the attached Manual Notice List.

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